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Special Issue on Rice Research in Asia

Guest Editor: **Balakrishna Pisupati**

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International Year of Rice: Follow-Up

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Special Issue on Rice Research in Asia

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A Letter from the Editors

Asian Biotechnology and Development Review (*ABDR*) was launched in 1997 with the purpose of providing to policy makers in developing countries analysis and information about developments in biotechnology to enable them to make informed choices. This journal makes an effort to assess the potential of biotechnology for economic and social development and delineates the complementarities that exist for South-South cooperation especially in the Asian context. *ABDR* has also made an attempt to identify the contours of biotechnology and in the process facilitated an inter-disciplinary dialogue between natural and social sciences which has provided a unique niche for *ABDR*.

This rather tall mandate has been catered to under the guidance of leading authorities from different regions and institutions who comprise the Editorial Advisory Board (EAB) of the journal. The EAB has now been joined by Dr. Se-Joon Yoon, Director, APCTT, New Delhi, and Prof. V. S. Chauhan, Director, ICGEB, New Delhi. The Editorial Board has also been joined by Dr. Balakrishna Pisupati, Head, IUCN, Regional Biodiversity Programme, Asia, Colombo, Sri Lanka and Dr. Ajay Parida, Programme Director-Biotechnology, M. S. Swaminathan Research Foundation, Chennai. While welcoming them on board, we look forward to their support.

At the occasion of the Second Conference on Biotechnology for Asian Development held in New Delhi in April 2004 an extended meeting of the Editorial Board and other leading experts on the subject discussed the ways and means of improving the effectiveness and sustainability of the journal. Among the valuable suggestions made at this meeting was a proposal of bringing out special issues of *ABDR* on specific themes edited by guest editors. In tune with this suggestion the current issue is a special issue focusing on rice research in Asia edited by Dr. Balakrishna Pisupati. Similarly, Dr. S. R. Rao of Department of Biotechnology, Government of India, Dr. Edgar DaSilva, Honorary Professor, University of Vrystaat, South Africa and Dr. Jose B. FALCK-Zepeda, IFPRI, Washington D.C. have kindly agreed to be the guest editors for some of the forthcoming issues.

The meeting also recommended making *ABDR* a subscription-based journal to strengthen its long term sustainability. We are introducing subscription beginning with this volume. The subscription rates have been kept nominal and are announced separately in this issue. So far *ABDR* has been sustained by RIS internal resources and with partial support from UNESCO, Paris and Department of Biotechnology, Government of India. We hope our readers and institutions would also come forward to support the journal through their subscriptions on the enclosed form. We also hope the readers would like the new color-scheme of the journal.

Sachin Chaturvedi
Managing Editor

Nagesh Kumar
Editor

Rice Research in Asia: An Introduction

Balakrishna Pisupati*
Guest Editor

With more than 2.7 billion people – most of them poor – relying on rice as their major source of food, it is but appropriate that the importance of rice is commemorated by declaring year 2004 as the 'Year of Rice'. According to the International Rice Research Institute (IRRI), the number of people relying on rice as a major source of food, would go upto 3.9 billion by 2025. Historians following rice cultivation and evolution record that it is the Asia region, more particularly the Korat region of Thailand, the longitudinal valleys of Myanmar, Southwestern China and Assam, that domesticated rice in early times. *Oryza fatua* was one of the early rice species that was recorded from the farmlands. Rice is perhaps the only grain that fed more people in history than any other crop. Asia accounts for 90 per cent of world's production and consumption of rice because of its favourable hot and humid climate.

Demand Specific Challenges

With increasing demand for qualitative production as against quantitative production, the benefits of cultivation of nutritionally rich rice varieties will be realized by farmers only if they get either better yield or market price. It is estimated that one-third of India's rice area was occupied by seven popular varieties. Fifteen per cent of this area was planted with varieties released before 1980 while farmers continued to plant traditional varieties on 19 percent of the area.[1] This demonstrates the need to breed varieties which have proven benefits for the farmers. The success of green revolution, many times, is attributed to the fact that adoption of new varieties by farmers was based on the proven yield increase and supportive extension service. New developments using rice biotechnology is still to reach that level of refinement to receive public support.

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Studies by IRRI and the International Food Policy Research Institute (IFPRI) indicate that the growing economic prosperity of Asia might force farmers out of rice cultivation due to poor returns and increasing costs of agronomy in the coming years. Reducing per capita availability of land, water and labour are also reducing the rice production in the world. However, to meet the projected demand, the rice production should go up by 70 per cent in terms of the yield during the next three decades. With 45 per cent of rice growing areas in the rainfed conditions, there is a potential for increasing yield from the current 2.0 t/ha to 5.0 t/ha, while in irrigated conditions, such potentials are limited.[2] Ensuring sustainable cultivation of rice, developing suitable production systems adapting to changing conditions and using the genetic diversity available are the key challenges we face today.

New Technologies

One of the possible options for further increases in rice production is through the application of new technologies such as biotechnology and improved agronomy, complimented by traditional farming systems that need to be adapted to changing environment and needs of local people. Rice improvement in many parts of the world, especially Africa and Latin America has benefited from some interventions of biotechnology such as embryo rescue and anther culture achieving yield and quality improvements.[3] Genetic engineering, supported by gene mapping, gene tagging and gene transfer techniques is emerging as a potential area in rice improvement. The rates of success, commercial application, socio-economic impacts of genetic engineering are often debated – some with facts and figures and some with assumptions. However it is true that biotechnology is certainly moving the pace of rice improvements both in terms of quantitative as well as in qualitative terms.

Undoubtedly rice biotechnology has seen much of advancements in the recent past. Small genome size of rice (about 430 Mb), availability of whole genome sequence (the first food crop for which such information is available)[4], proven public-private partnership in research, availability of genetically diverse germplasm have all contributed to this advancement in rice biotechnology. Studies on Quantitative Trait Loci (QTLs) mapping and Linkage Disequilibrium (LD) mapping have provided needed information on how gene combinations might work under specific environments against particular genetic backgrounds. Pyramiding of genes and multiline constructions in rice has proven to offer precise and authentic information on specific traits, including those controlled by polygenes. More than 60 cultivars belonging to indica, japonica, javanica and elite African cultivars have been used for transformation (genetic engineering) activities. Characters such as herbicide resistance, insect resistance, viral, fungal and bacterial disease resistance; tolerance to drought, salinity, chilling; fortification with micronutrients such as iron and vitamins (Vitamin A in particular) have all been subjected to genetic manipulation.[5] While commercialization of rice varieties that were genetically modified is still to reach critical levels[6], the potential is significant.

While progress in rice breeding using biotechnology seems promising, there are several challenges that still exist. These include: expanding the base of the beneficiaries of the technology, minimizing the risks associated with adoption of the technology for socio-economic systems at various levels industry to environment, misuse of genetic resources for privatisation of information and knowledge, impacts of regional and international trade on such products, linkages to emerging areas of nanotechnology and public good. Addressing these issues is complex given the multiplicity of actors involved and the capacities to address these issues. However, such complexity should not be an excuse for inaction.

Emerging Challenges

Risk assessment and management of genetically modified rice is not only a scientific issue but also a policy and socio-economic issue. Clear national policies on such issues of biosafety supported by suitable awareness raising and capacity building can only help future adoption of the technology and varieties developed through the technology. Consumer choice and public support are important to adoption of rice varieties modified through genetic engineering. Scientists and policy makers need to be clearer on the approaches used and be transparent in their efforts to support adoption of biotechnology. Similarly there needs to be a mechanism to ensure adequate exchange of fact and figures and as a society we assess issues more objectively. It is important here that the missing links between scientific facts and public opinion do not cost dearly the potential use of technology for rice productivity enhancement.

While the need for genetic diversity and characterization of such diversity is the backbone for any future improvements in rice – both by traditional and biotechnological means – the ability of countries to use the diversity for increasing local production is a critical challenge. The centers of origin of rice such as south and Southeast Asia need to work with local communities so that improving traditional cultivars become a potential option through interventions such as participatory plant breeding. Supporting such actions coupled with identification of markets for such varieties is sure to enhance the value of genetic diversity we all are proud of. This brings us to the issues related to trade and intellectual property rights (IPR) offer significant challenges to commercialization of genetically modified rice, the production and consumption patterns at national level would decide on who will use the produce and how. Maturing debates on issues o identifying sources and countries of origin of genetic resources through the Convention on Biological Diversity (CBD) and the World Intellectual Property Organization (WIPO) through debates on Access and Benefit Sharing (ABS) are bound to make issues of patenting and IPR protection more realistic and supportive of local needs. However, the challenges to trade in genetically modified rice will be to related to spread of unauthorized production of modified seed that offer production advantage circumventing biosafety norms, need for labelling and certification that will increase costs of products in the markets and, possible monopoly of certain regions of the world that can develop traits combining productivity with adoption due to technological advantages.

Way Forward

With Asia in the center of debates related to rice production and consumption in the coming decades, it is important that the region realizes the potential of emerging technologies such as biotechnology in feeding its population and achieving both sel-reliance and self-sufficiency in rice breeding. Regional efforts to join hands in forming a consortium to support further development and adoption of rice farming technology can be a possible option with countries like Thailand and Myanmar poised for continued expansions and increasing yields. Using integrated approaches to rice farming that include better use of water and being responsive to changing climatic conditions – both in irrigated and rainfed conditions – will be one area that will need more emphasis in the years to come. Recognising the innate genetic potential of traditional varieties that continue to grow in fragile environments and enhancing their yield are as important as supporting technological interventions in breaking potential of rice crop. Development of such varieties and recognition of such varieties through mechanisms such as farmers' rights will be critical for ensuring continued engagement of poor farmers in rice cultivation.

The International Year of Rice comes to a close in December 2004. However, the commemoration envisions rice as the focal point through which the interdependent relationships among agriculture, food security, nutrition, agro-biodiversity, the environment, culture, economics, science, gender and employment can be clearly assessed. This makes rice and its farming a challenge as well as an opportunity. Some of the challenges and opportunities include:

- **Enhancing food and nutritional security.** Although rice is a rich source of energy and protein, it has limited quantities of vitamins and other essential micronutrients. Nutrition can be improved by better rice processing and cooking techniques, the use of rice varieties with high nutritional values, and the fortification of rice with vitamins and minerals (e.g. through applying food technology). Countries should develop the infrastructure to support the responsible utilization of biotechnology and enhance support to increasing diversity in rice-based systems which greatly contribute to rural income and complete nutrition.
- **Improving the productivity of rice-based systems.** Sustainable quantitative and qualitative improvements to rice cropping requires: i) genetic improvements for higher yield potential, ii) better crop management techniques; iii) reduced post-harvest losses, and iv)development of integrated agronomic systems. To achieve these countries need capacity, through training and information exchange, and responsible ways of transferring technologies, including biotechnology.
- **Managing water resources.** There is growing concern about the sustainable availability of water that can be used for irrigation at

global level. Water scarcity can be addressed by reducing the quantity of water required (through developing new rice varieties or improved irrigation/agronomic systems) or by recycling water through multiple uses. The cultivation of rice in low-water regimes will lead to changes in water and nutrient management, cropping patterns and tillage practices. National water policies should be responsive to these issues.

- **Protecting the environment.** Environmental concerns in rice production include indiscriminate use of pesticides, inefficient use of fertilizers, and emissions of greenhouse gases. At the same time, rice-based ecosystems host a wealth of biodiversity, and the majority of the planting material used by poor farmers is derived from seeds that they produce themselves and that represent generations of local genetic resources. Traditional rice varieties and cropping systems should be integrated with modern practices to ensure rice cultivation is not only attractive to local resource poor framers but also justifies investments into continued conservation efforts.
- **Options for synergy.** The overall challenge for rice-based systems is to identify and execute synergetic solutions for rice development, and these are possible only if decision-makers, technicians, farmers and civil society are well aware of the many factors related to sustainable rice production. In addition, sound policies on rice development depend on the harmonization of diverse policy instruments, which are often under the auspices of different ministries. Synergies between instruments such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), CBD's Programme of Work on agrobiodiversity, the trade rules of World Trade organization (WTO), the principles of access and benefit sharing are a few of such policies that need better national integration to ensure rice cultivation remains relevant in the decades to come.

The experiences and directions provided in this special issue on 'Rice Biotechnology' offer some insights into the issues and relevance of rice to Asia. Not only the regional cooperation to conserve and utilize rice germplasm is important, but there is also need for recognition of the role of technology transfer in the region to achieve sustainable rice production systems in the years to come. What we need now is not only another revolution in increasing yields but a revolution in ensuring opportunities, awareness and information are more equitable and benefits of actions shared more equally. These need to be based on principles of support and respect to human well being and dignity so that we will have other opportunities to celebrate the role of rice in continuing human well-being.

Endnotes

[1] Janaiah and Hossain (2002).
[2] Hossain (1997) and IRRI (2004).
[3] UNDP-HDR (2001).
[4] Yu *et al.* Goff *et al.* Sasaki *et al.* and Feng *et al.* (2002).
[5] Giri and Vijaya Lakshmi (2000).
[6] Coffman *et al.* (2004).

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Some Imperatives and Challenges for Rice Biotechnology in Asian National Agricultural Research and Extension Systems

Edilberto D. Redoña* and Lou Franz G. Mula*

Rice in Asia

Rice, *Oryza sativa L.*, is the staple food for more than three billion people or over half the world's population (FAO 2004). It provides 27 per cent of the dietary energy supply and 20 per cent of dietary protein intake in the developing world. Grown in at least 114 mostly developing countries, rice is the dominant crop in Asia where it covers half of the arable land used for agriculture in many countries (Cantrell and Hettel 2004). Moreover, it is the primary source of income and employment for more than 100 million households in Asia and Africa (FAO 2004). The Asian continent, where 56 per cent of humanity including 70 per cent of the world's 1.3 billion poor people lives, produces and consumes around 92 per cent of the world's rice (Papademetriou 1999). Over 50 per cent of the 840 million people suffering from chronic hunger live in areas dependent on rice production. About 80 per cent of the world's rice is produced in small farms, primarily to meet family needs, and poor rural farmers account for 80 per cent of all rice producers (FAO 2004). Nine of the top ten rice producing countries in 2003, viz., China,

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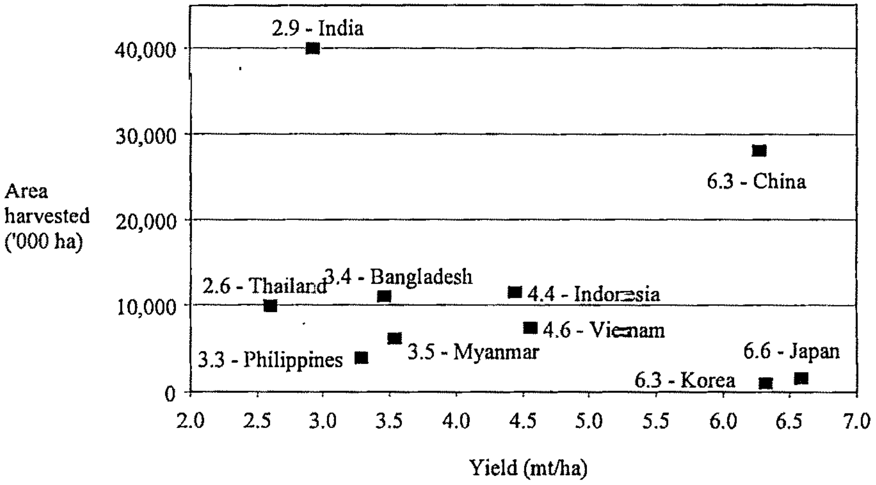
India, Indonesia, Bangladesh, Vietnam, Thailand, Myanmar, the Philippines, and Japan are in Asia. China and India combined account for more than half of the world's rice area and, along with Indonesia, consume more than three-fourths of the global rice production (Hossain 1997; Maclean *et al.* 2002). However, less than seven per cent of the world's rice production is traded internationally (Maclean *et al.* 2002) and, with this small marketable surplus, prices fluctuate widely with droughts, floods, and typhoons (Hossain 1997).

But more to being the world's most popular staple, rice has been cultivated by mankind for more than 10,000 years. Hence, it provides a symbol of global unity and cultural identity for many countries where rice cultivation is practically intertwined with religious observances, festivals, customs, folklore, and traditions. The United Nations, therefore, declared 2004 as the International Year of Rice, with a theme that captures the meaning of rice to so many peoples and cultures: Rice is Life.

The Challenge to Increase Rice Productivity

The Green Revolution beginning in the 1960s ushered in an era of high rice productivity, with yields doubling or tripling from 1.9 tonnes per hectare (t/ha) in many Asian countries (Figure 1). Between 1966 and 2000, the rice production growth of 130 per cent, from 257 million

Figure 1: Area harvested and yield levels (mt/ha) in major Asian rice-growing countries (FAO, 2003)



tonnes in 1966 to 600 million tonnes in 2000, outpaced the population growth of 90 per cent in low income countries. The average per capita food availability was 18 per cent higher in 2000 than in 1966 (Khush 2004). About 84 per cent of rice production growth has been attributed to the use of modern technologies such as rice varieties that are semi-dwarf, early maturing, non-photoperiod sensitive and can, therefore, be planted more than once a year, and responsive to nitrogen fertilizer (Maclean *et al.* 2002). More than 2,000 modern varieties, with resistance and tolerance to biotic and abiotic stresses, have been commercially released in 12 countries of South and Southeast Asia over the last 40 years (Cantrell and Hettel 2004). As a consequence, rice production cost per unit output was reduced by 20-30 per cent. This translated to reduced rice prices at the consumer level from about US$450 per metric tonne (mt) unmilled rice in the early 1950s to less than US$300 per mt by 1999 (Maclean *et al.* 2002), with world market rice prices decreasing by 80 per cent over the last 20 years (Cantrell and Hettel 2004).

In Asia, however, demand for rice is projected to increase by 70 per cent over the next 30 years, driven primarily by population growth that, excluding China, is expected to increase by 51 per cent (Hossain 1997). It is estimated that the Asian population will increase from 3.7 billion in 2000 to 4.6 billion in 2025 (Cantrell and Hettel 2004). In the Philippines, for example, the population is expected to reach 107 million by 2025 and 65 per cent more rice, relative to present levels, would need to be produced to keep up with demand by a population continually growing by 2.3 per cent each year. This translates to a required sustained year on year rice production growth of 3 per cent. Given that annual rice production growth rates have been decelerating to less than 2 per cent per year, and the land frontier, the primary source of growth in recent years is closing, major technological progress has to be achieved in the next two decades to avoid importation. Against a backdrop of decreasing land, labour, and water and rising prices of production inputs, the challenge to further increase rice productivity is indeed enormous.

Constraints in Asian Rice Production

Rice production and post-production processes in Asia are severely compromised by pests, diseases, and physiological and environmental factors. The rice crop, for example, is the world's single largest market for agrochemicals, consuming around US$3.7 billion annually, with agrochemical costs and crop losses amounting US$ tens of billions per year (DFID 2004). Tungro, the most destructive viral disease in Southeast Asia, for example, results in crop losses worth more than US $1.8 billion annually (DFID 2004). Moreover, rice cultivation per se is restrained by resource constraints, among the most important of which are the projected scarcity of water (Tuong and Bouman 2002) and scarcity of land. Technological progress is required to increase crop water productivity of rice (Cantrell and Hettel 2004) and rice crop productivity under fragile environments such as the rainfed lowlands and uplands.

Biophysical constraints account for substantial yield losses in Asia (Hossain 1997, Evenson *et al.* 1996) (Table 1). In the irrigated ecosystem, yield loss due to technical constraints accounted for 20 per cent (962 kg/ha) of the average yield, with soil-related problems being the most significant. On the other hand, yield loss due to technical constraints accounted for 33 per cent of average yield in the rainfed lowland and flood-prone ecosystems, with submergence being the most important, while it was more than 40 per cent of the average yield in the upland ecosystem, with drought being the most significant. Overall, all technical constraints caused a total yield loss of about 23 per cent or 833 kg/ha in Asia, with abiotic constraints being more important than biotic constraints for all ecosystems. Climate-related constraints like submergence, drought, and cold resulted in yield losses that ranged from 227 kg/ha (20 per cent of average yield) for the upland to 429 kg/ha (28 per cent of average yield) for the flood-prone ecosystems. Yield losses due to pests and diseases, on the other hand, were most significant in the rainfed ecosystem while, that due to weeds were most important for the upland environment.

The Role for Rice Biotechnology

Agricultural biotechnology in Asia has been recognized as having the potential to: (i) increase crop and animal productivity; (ii) improve nutritional quality; (iii) broaden tolerance of crops for drought, salinity, and other abiotic stresses; and (iv) increase resistance of crops to pests and diseases (ADB 2001). In the case of rice biotechnology, the Rockefeller Foundation (RF), in the process of developing its International Programme on Rice Biotechnology or IPRB (Evenson *et al.* 1996, O'Toole *et al.* 2001), identified the top-20 priority traits for biotechnology research intervention, balancing research costs vis a vis the benefits from expected increases in rice productivity or value.

Table 1. Yield loss due to technical constraints in the rice ecosystems of Asia (Evenson et al 1996).

Constraints	Irrigated (kg/ha)	Rainfed lowland (kg/ha)	Flood-prone (kg/ha)	(kg/ha)	Average for AsiaLoss	
					Upland (kg/ha)	Loss (%)
Biotic						
Diseases	69	146	18	70	83	3.1
Insects	108	166	16	65	110	2.3
Other pests	29	88	21	120	52	1.4
Abiotic						
Water	400	288	429	227	358	9.9
Soil	356	75	13	80	229	6.4
Total	962	763	496	563	833	23.1
Loss as % of yield	19.6	33.2	33.1	40.2	23.1	

Guided by this prioritization, the RF in the mid-1980s supported a 17-year programme that laid the scientific foundation for 'rice biotechnology' as we know it to-day. At about the same time, Asian national agricultural research and extension systems (NARES) began building biotechnology capacity. Among the important accomplishments of the IPRB were: (i) the generation of the first DNA molecular marker map of rice; (ii) the regeneration and transformation of rice; (iii) the use of rice pest genomic information to understand host-plant resistance; (iv) discoveries that changed the way rice geneticists viewed breeding objectives such as insect resistance, abiotic stress tolerance, and hybrid rice; (v) the discovery of rice's pivotal genomic position in the evolution of cereal species; (vi) the transfer of the resulting biotechnologies to institutions in rice-producing and -consuming countries; and (vii) the strengthening of both physical and human resources in cooperation with national and international rice research systems in Asia, Africa, and Latin America (O' Toole *et al.* 2001). The latter involved international collaborative research-cum-training that successfully linked emerging national rice biotechnology efforts directly to advanced research institutes in the United States, Europe, Japan, and Australia, resulting in the training of more than 400 rice scientists, primarily from Asia, in advanced laboratories around the world. At least 73 institutions in 12 Asian countries received both research grants while having up to 20 of their scientists sent to formal training activities that included: (i) Ph.D. fellowships; (ii) dissertation fellowships; (iii) postdoctoral fellowships; (iv) visiting scientist fellowships; (v) biotechnology career fellowships; and (vi) technology transfer fellowships in advanced laboratories and universities in developed countries (O' Toole *et al.* 2001).

Beginning 1993, the Asian Rice Biotechnology Network (ARBN) was also formed, with IRRI as coordinator, and this facilitated research collaborations amongst several Asian rice breeding programmes with a primary objective of developing disease resistant varieties through the application of DNA marker technology (Leung *et al.* 2004). Among the major Asian R&D institutions involved in the ARBN were the Indonesian Agricultural Biotechnology and Genetic Resources Institute, the Central Rice Research Institute in India, the Punjab Agricultural University also in India, the Philippine Rice Research Institute (PhilRice), the Agricultural Genetics Institute in Vietnam, and the China National Rice Research Institute (CNRRI).

Progress in Rice Biotechnology Applications

With increased activities on rice biotechnology beginning in the mid-1980s, rice gradually became the 'model monocot plant' in molecular genomics research, eventually becoming the first food crop for which complete genome sequence became available. Progress achieved in the application of biotechnology for rice improvement has been in two major areas-the use of molecular markers for identifying and incorporating favourable genes within the rice species, and the use of transgenic technologies to incorporate traits for herbicide tolerance, biotic stress resistance, abiotic stress resistance, and nutritional value into rice (Coffman *et al.* 2004, Leung *et al.* 2004).

Use of molecular markers. The development of the first rice molecular map in the late 1980s (McCouch *et al.* 1988) sped up molecular genetics research in rice. Among the early molecular marker applications for rice improvement were the: (i) construction of dense genetic maps using different populations; (ii) tagging and/or introgression of major genes and those underlying quantitative traits, referred to as quantitative trait loci (QTL); (iii) high-resolution characterization and fingerprinting of germplasm; (iv) assessment of the diversity of germplasm pools; and (v) map-based gene cloning. Molecular markers offered great potential for increasing the precision and speed of rice breeding as, among other advantages over phenotypic markers, they provided the ability to (i) screen breeding populations regardless of growth stage; (ii) screen for traits that were extremely difficult, expensive, or time consuming to score phenotypically; and (iii) distinguish the heterozygous condition without need for progeny testing (Coffman *et al.* 2004). Molecular markers provided geneticists with powerful tools to dissect the inheritance of economically important traits in rice, many of which are quantitatively inherited and complex in nature. Thus, studies dealing with QTL were carried out such as those involving tolerance to a variety of environmental stresses including drought, seedling vigour, submergence, salinity, and mineral deficiencies or toxicities (Champoux *et al.* 1995, Price *et al.* 2002, Redoña and Mackill 1996, Xu and Mackill 1996, Flowers *et al.* 2000, Gregorio 2002). These traits were considered primary targets for molecular marker-aided selection (MAS) as breeding for them using conventional techniques often proved to be difficult.

MAS or the selection of traits based on the presence or absence of a molecular marker or markers in lieu of phenotype has already received a lot of emphasis in rice. The development of simple and less costly marker systems based on the polymerase chain reaction (PCR) such as the simple sequence repeats or SSRs (McCouch *et al.* 2002) contributed greatly to the use of MAS in various laboratories in developing countries. For example, at PhilRice, the NARES for rice in the Philippines, MAS studies are conducted to develop varieties resistant to bacterial blight, including the pyramiding of two to three bacterial blight resistance genes in a common genetic background, both for inbred and hybrid rice breeding. Gene pyramiding is expected to provide durable resistance against rice insect pests and diseases and attempts in this direction have been tried early on for bacterial blight and rice blast diseases (Yoshimura *et al.* 1995, Hittalmani *et al.* 1995) and the insect brown planthopper (Su *et al.* 2002). Introgressing genes from wild relatives into cultivated rice has also been accomplished with the aid of molecular markers, such as the bacterial blight resistance gene from *O. longistaminata* (Ronald *et al.* 1992), and the yield traits from *O. rufipogon* (Thomson *et al.* 2003). Markers have also been used to minimize the linkage drag that occurs in wide crosses and to obtain the desired recombinants in fewer generations during backcrossing (Takeuchi *et al.* 2003, Blair *et al.* 2003). Whole-genome, marker-based selection allows for new opportunities to unravel and makes efficient use of genetic variation both in cultivated rice and its wild relatives.

One of the most significant developments aided by the use of molecular markers in rice was the map-based cloning of *Xa 21* and its subsequent use in developing varieties with broad spectrum resistance to bacterial blight (O'Toole *et al.* 2001). Starting with the genetic mapping using RFLP makers of the *Xa 21* locus in 1990 (Ronald *et al.* 1992), the gene was cloned using map-based cloning techniques and a bacterial artificial chromosome library by 1995 (Song *et al.* 1995, Wang *et al.* 1995). By 1997, the gene had been pyramided with other *Xa* genes using PCR-based MAS (Huang *et al.* 1997) and, by 1998, *Xa 21* had been transformed into elite lines (Zhang *et al.* 1998) with field trials conducted in China, India, and the Philippines by 1999 (Rockefeller Foundation, 1999). By 2000, a hybrid rice parental restorer line had been improved through MAS, resulting in resistant hybrid rices under field conditions (Chen *et al.* 2000).

The IRRI-coordinated Asian Rice Biotechnology Network that was supported by ADB and the RF played a key role in developing capacity for marker-aided analyses of pathogens and host plant resistance in several national breeding programmes. This network approach was found essential for the sharing of resources and providing sustained training in the adoption of new biotechnology tools and genetic knowledge in individual breeding programmes of different NARES in Asia (Leung *et al.* 2004). As a result of ARBN activities, elite or commercial rice lines with multiple disease resistance genes have been developed in several participating countries (Table 2).

Use of transgenic technologies. No genetically modified (GM) or transgenic rice has yet been commercialized in Asian countries. However, two GM rice, both involving herbicide tolerance, have already passed regulatory approval processes in the US: the Liberty-Link™ rice of Aventis Crop Science (now Bayer CropScience) involving phosphinothricin (PPT) herbicide tolerance, specifically glufosinate ammonium, and the CLEARFIELD™ rice involving imidazolinone herbicide tolerance from BASF Inc. (AgBios 2004). Ten trials in 11 hectares and 12 trials in 45 hectares were conducted in 2002 and early 2004, respectively, 90 per cent of which involved Monsanto (Jia *et al.* 2004). To indirectly gauge the extent to which the use of GM technology had so far advanced in rice, Coffman *et al.* 2004) utilized information on patent applications and classified these into the areas of: (i) herbicide tolerance; (ii) biotic stress resistance; (iii) abiotic stress resistance; and (iv) nutritional traits. Until 2002, 307 patents on rice biotechnology from 404 different groups had been filed (Brooks and Barfoot 2003). The largest number of patents was held by DuPont/Pioneer (68), followed by Monsanto (33), Syngenta (32), Bayer (19), public sector institutions in Japan, and Japan Tobacco.

Amongst various traits, herbicide tolerance has been the major focus for the private sector. In the US, Monsanto and Bayer were responsible for 80 per cent of GM rice field trials, primarily addressing herbicide tolerance (Brooks and Barfoot 2003). Other countries where herbicide tolerant GM rice has been field tested include Italy, Brazil, Argentina, and Japan, and possibly China (Coffman *et al.* 2004). Biotic stress resistance, on the other hand, has been the primary focus for public sector research institutions including those in Asia (Brooks and Barfoot 2003). Specific traits being worked on using GM technologies include resistance to bacterial blight using the gene *Xa*21, rice blast, rice hoja blanca virus, rice tungro spherical virus, rice yellow mottle virus, rice ragged stunt virus, the brown planthopper, and yellow stem borer, the latter, using *Bt* technologies, being the closest to commercialization. For abiotic stress tolerance, transgenic rice plants that produce trehalose at 3-10 times the normal rate, resulting in tolerance to drought and/or salinity have been developed by introducing the *ots A* and *ots B* genes for trehalose biosynthesis from *Escherichia coli* into rice (Garg *et al.* 2002). In China, Chinese researchers have developed several GM rice varieties that are resistant to the country's major rice pests and diseases, such as the stem borer, bacteria blight, rice blast fungus and rice dwarf virus. Significant progress has also been made with drought - and salt-tolerant varieties of GM rice, which have been in field trials since 1998 (Jia *et al.* 2004).

Perhaps one of the most promising, despite controversies, application of transgenic technology in rice has been the development of Vitamin A-enriched rice, popularly known as Golden Rice™ due to the slight yellow color conferred on the rice endosperm in transgenic grains (Potrykus 2000, Beyer *et al.* 2002). Vitamin A is considered as absolutely essential for children and women of child bearing age and, worldwide, nearly 134 million children are at risk for diseases related to Vitamin A deficiency (VAD), including some 3.1 million preschool age children who suffer from eye damage, and nearly 2 million children under 5 years of age that die each year from diseases linked to persistent VAD. In Southeast Asia alone, 5 million children become at least partially blind every year due to VAD. Golden Rice™ has the potential to improve the supply of Vitamin A in the human diet, thereby alleviating the suffering and death of millions of people, especially those who cannot afford diet diversification (ISAAA 2004a). New Vitamin A-enriched materials with up to ten times more the level of pro-Vitamin A are now in the pipeline, including several popular Asian indica varieties such as IR64. Reported to involve "clean" events, without cross-border transfers or antibiotic markers, the new materials are being readied for backcrossing and stability and field testing in 2004, while vitamin A absorption and bioavailability tests are underway or planned in the Philippines, China, and the USA (Datta *et al.* 2003, Coffman *et al.* 2004, Cantrell and Hettel 2004).

Another promising use of transgenic technology to improve human nutrition is in combating iron deficiency, one of the most widespread micronutrient deficiencies worldwide. Deficiency to iron in the human diet affects about 3.5 billion people worldwide and could result in illnesses such as anemia, heart problems, and neurological disorders. The ferritin gene from *Phaseolus vulgaris* has already been introduced into rice, resulting in the doubling to tripling of the iron content in the rice endosperm, even after polishing the grain (Vasconcelos *et al.* 2003). To improve the bioavailability of iron, since it is usually in complex with phytic acid, the genes from *Aspergillus fumigatus* encoding a thermotolerant phytase protein and the endogenous cysteine-rich metallothionein-like protein were also introduced into rice resulting in a 7-fold increase in cysteine level and a 130-fold increase in phytase level in the resulting transgenic plants (ISAAA, 2004b).

Many NARES in rice-growing countries of Asia are actively involved in the use of transgenic technologies, encouraged by government policies supporting biotechnology research, and endowed with universities and agricultural research institutes with biotechnology research capacity. In a recent study done by the International Food Policy Research Institute (Atanassov *et al.* 2004), 209 transformation events were reported to have already been done in 76 scientific institutes in 16 countries. Of these, 109 (52 per cent) were done in 7 Asian countries, viz., China (30), Indonesia (24), India (21), the Philippines (17), Thailand (7), Pakistan (5), and Malaysia (5). Of these countries, however, only the Philippines had so far approved the commercial release of a transgenic food crop – a Bt-enhanced corn. Although the highest number of transformation events for any crop was reported for rice (17.7 per cent), followed by potatoes (11.0 per cent), maize (8.6 per cent), and papayas (6.2 per cent), a GM rice variety has yet to be commercialized in Asia.

In the Philippines, both IRRI and PhilRice have on-going rice biotechnology programmes employing molecular marker and transgenic technologies, as well as other more conventional techniques such as in vitro culture and wide hybridization. With the Philippine government declaring a policy supportive of biotechnology research, the use of biotechnology is embedded as a strategy for achieving the goals set by the irrigated lowland, direct seeded, rice for fragile environments, and hybrid rice multidisciplinary R&D programmes of PhilRice. GM technology, in particular, is being used to improve high-yielding varieties, including NPTs and hybrid rice parental lines (Aldemita *et al.* 2004). The Philippine focus is on the tungro, sheath blight, blast, and bacterial blight diseases, as well as on the insect stemborer and tolerance to salinity. Genes procured from laboratories around the world and modified for *Agrobacterium tumefaciens*-mediated transformation, are being used to generate transgenic plants. A number of transgenic plants that contain chitinase and glucanase genes have already been produced and tested under controlled screenhouse conditions. Moreover, PhilRice has conducted the first and only contained field trials for any GM rice in the Philippines where the transgenic IR72 plants containing the *Xa*21 gene for bacterial blight resistance showed complete resistance against nine Philippine races of the pathogen. On the other hand, transgenic plants with the *pin*2 gene are being developed to improve stemborer resistance, while a coat protein gene from the rice tungro bacilliform virus is being used in *A. tumefaciens*-mediated transformation. PhilRice is also a member of the Golden Rice™Network and undertook backcrossing activities on the now discarded original Golden Rice™materials. To hasten the availability of vitamin-A enriched rice to consumers, PhilRice hopes to continue its active participation in this network that involves other Asian countries such as Indonesia, Vietnam, India, Bangladesh, and China, as well as partners in developed countries such as the US, Germany, UK, and Switzerland. Already, guidelines are on the national testing of GM rice prior to commercialization are being prepared. To hasten public acceptance of biotechnology, in general, and GM rice, in particular, PhilRice, along with other Philippine government agencies, has also been spearheading a massive public education campaign using the tri-media as well as various public fora involving the government, private, NGO, and religious sectors.

Work in progress. Advances being made in the field of functional genomics will provide ample scope to further increase yield, build plant protection, improve nutrition, and enable rice to grow using less water and in adverse environment. The availability of the complete rice genomic sequence offers a lot of opportunities to further understand the natural genetic variation and the effects of alleles, and their interactions, for traits that are important in rice breeding, using specific genetic backgrounds and under specific environments. At IRRI, for example, biotechnologists are systematically assessing the array of phenotypes resulting from the disruption of putative gene sequences in mutants, near-isogenic lines, permanent mapping populations, and elite and conserved germplasm through a functional genomics initiative (Hossain *et al.* 1997, Leung *et al.* 2004). However, these gene discovery and allele mining efforts would require the annotation of the rice genome and the subsequent build up of databases and information resources. The use of information and communication technology and bioinformatics, such as the IRIS (Bruskiewich *et al.* 2003; http://

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www.icis.cgiar.org/) and GeneFlow (www.geneflow.com) databases, should make the mounting information more easily accessible to scientists, especially breeders in rice-growing countries.

Other work in progress include studies designed to transfer the C_4 photosynthetic pathway and leaf anatomy genes of maize to C_3 rice in order to improve the rice plant's radiation use efficiency while reducing transpirational water loss and N fertilizer requirement, and studies aiming to more deeply understand the genetic variation for drought tolerance using genomics and bioinformatics tools in order to identify the exact genes involved (Cantrell and Hettel 2004). Another promising area is the genetically engineering of N2 fixation capacity into rice and, in this direction, attempts to engineer the nif-regulon into the chloroplast genome have been made with the idea of not having to make rice totally independent of external nitrogen supply, but to provide additional nitrogen during the grain filling period to rescue the photosynthetic apparatus for a longer period of time (Potrykus 2000). Over the medium- and long-term, the apomixis research that earlier had been started at IRRI, would need to be vigorously pursued using biotechnology in order to capture and made available to resource poor farmers the benefits of heterosis.

With over 27 million tonnes of rice worth US$5560 million lost annually due to pests such as the stem borer, sheath blight, and bacterial blight, GM rice solutions are nearing commercialization to help offset this yield loss. Ready for field evaluation are Bt/hybrid rice in China and India; XA rice in China, Philippines and India; Golden rice in the US, the Philippines and India; and herbicide tolerant rice in Spain, USA, and China. For commercialization by 2005-06 will be Bt rice in China, and Golden Rice and Ferritin or high- iron rice by 2007-08 (Datta 2004).

Issues, Concerns, and Opportunities

Explicit governmental biotechnology agenda. There is a need for many Asian rice-growing countries to develop clear and time-bound national agenda for biotechnology R&D and commercialization. For example, in the Philippines, a technology explicit and market driven national development agenda, which recognizes the role of science and technology in promoting economic development and facilitating trade is desired, along with corresponding increased investments in R&D (Padolina 2004). This could be achieved by developing a collaborative scheme that shall bridge the academe and science and technology community with industry, and having both well tuned to market demands. There is also a need to emphasize the role of the government in formulating technology policies and plans, as well as funding of research and development projects; the role of academe in identifying what problems need solving, and the role of the private sector in investing research that could meet the country's immediate needs.

In the case of India, for the first time, a specific impetus has been given to the advancement of biotechnology. In the country's 2005-05 budget, the Minister for Finance emphasized that science and technology, including biotechnology, "will receive priority and will be provided with additional funds." A specific provision was given for companies doing scientific R&D approved by the Department of Scientific and Industrial Research before April 1, 2004 to be entitled to 100 per cent deduction of profits for 10 years. The Federation of Indian Chambers of Commerce and Industry noted that this will favour small and medium biotechnology companies who can channel savings to augment R&D activities (Crop Biotech Update 2004a).

The Agricultural and Development Economics Division (ESA) of the Economic and Social Department of the United Nations' Food and Agricultural Organization (FAO) showed that most of the research institutions in China, Cambodia, and Indonesia are in the initial states of developing biotechnology research capacity. The proportion of biotechnology expenditures to the total agricultural research expenditures is very small, and mainly from the public sector. The report discusses the importance of secured and sustained public research capacity including physical, human and financial, in the successful development of biotechnology innovations. For instance, countries like China, India, Indonesia, Malaysia, Philippines, Argentina, Brazil and Bulgaria have made significant investments in biotechnology research and regulation. Experience with genetically modified organism (GMO) testing for a wide array of locally important traits, and commercialization in these countries is growing, and government support programmes and policies actively encourage biotechnology R&D.

In China, scientists have released a report urging the central government to allow the commercial planting of genetically modified (GM) rice (Zhu 2004). They note that GM rice technologies are technically mature and are ready to be commercialized. GM products include several rice varieties resistant to China's major rice pests, including those that can resist the stemborer by using *Bacillus thuringiensis* (Bt), delta endotoxin and cowpea trypsin inhibitor CpTI genes, a protease inhibitor rice, a planthopper and bacterial leaf blight resistant rice using the Xa21 gene, and fungus-resistant rice (The Business Daily Update, 2004). The country currently has the largest field for GM rice trials. An estimate of about 25-30 per cent of China's plant biotechnology investments are spent on GM rice programmes (Zhu 2004). China has increased its budget for research and field trials of GM rice since 2001. Its biotech budget for 2001-2005 is $1.2 billion, a 400 per cent increase compared with 1996-2000. About $120 million out of the current budget is devoted to GM rice programmes (Jia *et al.* 2004). The Chinese Government has become the world's second-largest spender on plant biotechnologies, next only to the United States and the country is expected to launch at least 10 GM rice field trials by 2005 and release *Bacillus thuringensis* (Bt), cowpea trypsin inhibitor gene, and *Xa21* gene GM rices that year. Already, field trials in Hunan and Fujian provinces showed that GM rice boosted yields by 4 to 8 per cent, and allowed an 80 per cent reduction in pesticide use (Crop Biotech Update 2004d).

Setting the biotechnology R&D priorities. It may be argued that most of the earlier rice biotechnology activities, particularly in the public sector and on transgenic technology applications, were more science-driven and researcher-driven than attuned to the needs of ordinary farmers. It is important to note that for GM rices to be useful, at least in the immediate term, and to gain fast acceptance amongst resource poor farmers, it is best that they be derived from varieties already widely grown and suited to specific agroenvironments (DFID 2004). Ranged against the challenges confronting rice cultivation in most Asian rice growing countries today, it is clear that international as well as NARES biotechnology research should focus, on one hand, on the most important rice diseases and pests, and physiological and environmental factors that reduce rice productivity and quality as discussed earlier, and on the other hand, on increasing rice yield potential. An example of trait prioritization for rice biotechnology research in Asia, aimed at delivering the greatest impact on the lives of poor rice farmers and consumers, while being complementary to conventional rice improvement efforts, has been put forward by Hossain *et al.* (1997, Table 3). To ensure relevancy of biotechnology R&D agenda, a bottom-up approach needs to be implemented in the crafting of R&D priorities, where farmers' and other stakeholders' needs and concerns are adequately addressed. Such approach should benefit from the rich

Table 3. Prioritization of traits for biotechnology intervention in different rice growing environments (Hossain et al 1997).

Priority traits		Target environment	Available products breeding	Preferred approaches*		
				Conventional selection	Marker-aided	Transgenic
Stresstolerance	Bacterialblight	Rainfedlowland transgenic lines	Genes,markers,	++	++++	++++
	Sheathblight	Irrigated,High yield	Transgeniclines	+	+	++++
	Blast	Upland	Markers	+++	+++	+
	Stemborer	All	Transgeniclines	+	0	++++
	Drought	Rainfedlowland, Upland	Underdevelopment	++	+	+
	Salinity	Coastal areas		+++	+	++
Nutritionalvalue	Vitamin A		Geneconstructs,	+	0	++++
		transgeniclines				
	Fe		Geneconstructs	+++	0	+++
	Zn			+	0	?
Yield enhancement		All ecosystem	Elite lines	++++	++	++

*More '+' marks indicate higher priority; 0 = not applicable.

indigenous knowledge of local farming communities on specific rice production constraints while facilitating public acceptance and ensuring the trickling down of benefits from biotechnology-derived products. The extent to which biotechnology may improve food security does not settle the question of its relevance to quality of life; it is essential to move stakeholder involvement upstream in setting research priorities and to fairly share benefits through appropriate infrastructure and ownership arrangements (Chadwick 2004).

Need for more public investments. There remains an imbalance on R&D investments on rice biotechnology that tend to favour developed countries, thus impacting on the potential of biotechnology to boost agriculture in the developing world and alleviate the plight of resource-poor rice farmers in Asia. The concentration of biotechnology R&D in developed countries and the limited private sector effort in developing countries, particularly in Asia, has raised concerns over the economic concentration of biotechnology in favour of developed countries and multinational companies (ADB 2001). As the private sector would be unlikely to undertake rice biotechnology research based primarily on the pressing needs of resource poor farmers, due to difficulty in recovering costly investments, there is need for significant public-sector funding initiatives if benefits are to reach resource-poor farmers in developing countries in order for them to develop pro-poor biotechnology R&D agenda. Furthermore, public research products would have to gain similar approval as those developed by the private sector if transgenic research products and their associated potential benefits are to reach the poor. In this context, it will be necessary to work with local communities to ensure acceptance and adoption from the bottom up rather than simply again trying to impose viewpoints from the top down. Thus, needs must be identified – nutritional and environmental– so that product traits are country- elevant (National Agricultural Biotechnology Council 2004).

While Asian scientists have demonstrated the capacity to successfully undertake biotechnology R&D relevant to the needs of resource-poor farmers, the desired phenotypes have been few when compared to traits being developed by multinational firms and advanced research institutes in the developed world (Nuffield Council on Bioethics 2004). One bright spot, however, has been the case of Thailand that established the National Center for Genetic Engineering and Biotechnology (BIOTEC) in 1983. BIOTEC has supported biotechnology

R&D in six areas, including the improvement of disease resistance in rice, particularly rice blast. This disease affected 200,000 hectares of rice in Thailand in 1993, causing serious economic loss and resulting in government intervention to assist disease-struck farmers worth about US$10 million. Since then, BIOTEC has supported research for the molecular genetic characterization of local blast isolates and mapping of resistance blast genes, with focus on aromatic varieties for Thailand's export rice market. In 1999, BIOTEC also provided US$3.7 million to fund the 'Rice Genome Project Thailand', particularly for the sequencing of rice chromosome 9 that contains a QTL for tolerance to a very important concern of Thai rice farmers-submergence (Tanticharoen 1997). Most rice growing countries in Asia, with the exception of China and India (Atanassov *et al.* 2004), however, have yet to launch similarly focused government initiatives on rice biotechnology R&D. In China, investments on public sector biotechnology research has risen dramatically to $1.2 billion for 2001-2005, a 400 per cent increase over 1996-2000 levels, with about $120 million allocated for transgenic rice R&D (Jia *et al.* 2004). With field testing on various transgenic rices already going-on since 1998, with 53 hectares planted in 2003, China is poised to becoming the first country in the world to commercialize transgenic rice.

Importance of collaborations. Given the varying biotechnology research capacities of rice-growing NARES and the limited resources allocated for biotechnology research in the public sector, unintentionally encouraged by the phasing out of the IPRB of the Rockefeller Foundation (O'Toole *et al.* 2001), the constraints in NARES R&D budgetary allocations, and the reduction of funding support for international agricultural research centers (IARCs) such as IRRI (Cantrell and Hettel 2004), the need for biotechnology R&D practitioners to collaborate has become paramount. Collaborations need to be pursued at the individual, institutional, governmental, bilateral, regional, and international levels to ensure not only that the highest returns for R&D investments are attained, but also to facilitate regulatory approvals and biotechnology product commercialization. At the national level, the creation of a national coordinating body such as BIOTEC in Thailand (Tanticharoen 1997) should provide a mechanism for increasing efficiency in the use of limited national R&D budgetary allocations through the avoidance of research duplications and sharing of in-country research capacities. In the Philippines, the recent creation of a Crops Biotechnology Center under the Department of Agriculture augurs well for the development of a unified biotechnology R&D agenda for the country's priority crops, including rice, and the optimization of the use of limited manpower and logistical resources. On the other hand, a regional collaboration approach, as exemplified by the ARBN (Leung *et al.* 2004) should be able to develop a biotechnology R&D agenda focused on the shared needs of rice farmers in the region and, where possible, human pool, scientific, and financial resources or, alternatively, parcel out the research portfolio as was done in the rice genome sequencing initiative. One type of formal collaboration that has yet to be explored involves bilateral arrangements between countries. In the development of transgenic technologies, these South-to-South collaborations would be facilitative to the build-up and sharing of common approaches, genes, germplasm, regulatory trials, and biosafety-related information (Atanassov *et al.* 2004). The already established broad-based regional cooperation, such as the Association of Southeast Asian Nations (ASEAN) and the Asia Pacific Economic Conference (APEC) should be tapped to support these regional biotechnology undertakings. At the international level, programmes that help rice scientists from developing countries to train, further hone their capacities, and maintain ties with advanced laboratories at IARCs and developed countries need to be supported. For instance, India's Department of Biotechnology (DPT) and the United States for International Development have signed a letter of intent to initiate enhanced cooperation in agricultural biotechnology research and development. The partnership will pursue agri-biotech research projects including technology development, technology diffusion, biosafety, and related policy activities. In addition, joint workshops, conferences, scientific exchanges, and training of scientists will also be done. The programme will increase the "range of safe and environmentally sound technological options to producers and consumers of agricultural products" (Crop Biotech Update 2004a).

Role of IARCs and the private sector. Without formal, dynamic, and synergistic interfaces between the public and private sectors, much of the benefits of crop biotechnology will not reach those who need them the most. The sharing of information and experiences across sectors is crucial to facilitate the flow and process that technologies undergo from the laboratory to the farm (Crop Biotech Update 2004b). With many NARES still not fully enabled to undertake, solely by themselves, activities spanning the whole biotechnology research, development, and commercialization spectrum, IRRI and similar international institutions will still need to play their roles as technology and knowledge providers, as well as builders and enhancers of biotechnology capacities of rice-growing NARES. Of particular importance for IRRI is the provision of strategic research outputs that already several NARES in Asian countries are capable of transforming into applications and products. These could include protocols, gene constructs, and markers for traits relevant to local problems but prohibitively expensive for NARES to develop by themselves. Alternatively, IRRI should be able to complement its strategic research programme with a product development thrust, focusing on biotechnology-derived advanced breeding lines and varieties, with traits that have common high relevance amongst Asian countries. The product development portfolio could include varieties tolerant to drought, of high nutritional value, and resistant to major diseases such as tungro and bacterial blight. The role of IRRI as facilitator in the transfer of useful technologies and products amongst NARES through the sharing of technologies, knowledge, and experiences need to be strengthened. Equally important is its role in facilitating the formation of effective NARES/public sector and private sector collaborations, for NARES to be able to access private sector-held intellectual property (IP) on rice biotechnology processes and products. IRRI can also serve as a clearinghouse for IP-protected technologies from both the public and private sectors that NARES can easily access. Training support by IRRI and similar institutions for NARES should now also include those designed to advance NARES capacity on the science and management of biotechnology, IPR, biosafety and food safety regulation, and international negotiations. As Cantrell and Hettel (2004) argued, with IRRI's strengths, it can serve as the unbiased broker and facilitator amongst the rice NARES, advanced research institutions, and the private sector.

Other international organizations, such as the FAO, can help expedite rice biotechnology progress in Asia by promoting and supporting networking mechanisms such as the South-to-South cooperation model. They can also help in developing and supporting infrastructure for public-good agricultural research, providing knowledge and training to NARES researchers, enabling interactions amongst biotechnology stakeholders through dialogues and similar fora, facilitating access to relevant IP, sensitizing policymakers on biotechnology-related issues, and assisting governments in the crafting of biotechnology-related policies. As the primary source of GM crops continues to be the private sector, technology transfer between private and public sectors, in terms of products as well as experiences on regulation, commercial development, and release of GM crops, would greatly benefit NARES. This technology transfer can be facilitated by private foundations such as the International Service for the Acquisition of Agri-Biotech Applications (ISAAA).

Intellectual property rights (IPR). The impact of IPR on biotechnology research is often imbedded in discussions on public and private sector partnerships. There is a need to balance the fact that on one hand public sector institutions, due to limited resources, cannot fully avoid accessing private sector-held IP during the development of its own products and, on the other hand, the private sector has to avail of IPR protection to be able to protect its investments and commercial interests as well to be able to share their IP with other sectors without fear of exploitation. The development of the Golden Rice™ is a case in point. In total, 70 IPRs and technical property rights (TPRs) belonging to 32 different companies and universities were used in product development and for which 'freedom-to-operate' situations had to be applied for in order for NARES to begin using Golden Rice™ in further breeding and in de novo transformation activities using locally adapted varieties (Potrykus 2000). Several modalities, however, are still open to the public sector to be able to access genes and technologies from the private sector. These include direct purchase of genes and technologies, licensing, the fact that patents have time limits, confidential agreements, and the purchase of genes for incorporation into local germplasm. New types of IP agreements have also evolved, such as the donation of IP facilities and 'humanitarian' use type agreements as were done with Golden Rice™ with the threshold for humanitarian versus commercial use being a $10,000 income from the technology. The agribusiness giant Syngenta recently announced that it would donate new Golden Rice seeds and lines to the Golden Rice Humanitarian Board, including scientific results of the first field trials, as well as the technology, rights, and research results (Crop Biotech Update 2004d).

As the issue of IPR is likely to become increasingly important, the capacities of governments or the science sectors of many developing countries to understand, deploy, and negotiate regarding biotechnology need to be strengthened. Rice biotechnology practitioners in Asia need to be trained on the details of modern IPR systems and on negotiating with institutions and companies for the purpose of accessing IP, and applying for IP protection. Alternatively, research institutions could establish IP units, not only for negotiating with other institutions and sectors, but also for the IP registration of their own biotechnology processes and products.

Regulatory requirements. National biosafety committees in developing countries have made impressive progress in the drafting and implementation of biosafety regulations for the importation and testing of transgenic crops, with regulations for field tests already in place in rice-growing countries such as China, India, Thailand, and the Philippines (Atanassov *et al.* 2004). A looming issue, however, revolve around the compliance costs for regulatory approval that could prohibit many developing country institutions. In the various studies cited by Atanassov *et al.* (2004), annual compliance costs, including initial greenhouse and field screening, field testing for environmental impact, and food safety, but excluding technology development costs, ranged from US$140,000 for a virus-resistant papaya in Brazil to US$830,000 for a virus resistant potato in South Africa. For rice, an annual regulatory compliance cost of US$680,000 was estimated for a virus resistant variety in Costa Rica (Sittenfeld 2002) covering tests on molecular characterization and epidemiology, transgenic field trials, biosafety, IPR, food safety deployment, and gene flow. Given reduced NARES budgets, this could pose a major hurdle in the commercialization of rice biotechnology products from the public sector. It is hoped, however, that as knowledge and experience is gained by regulatory agencies, approval costs may decrease, both by reducing the number of required tests, and by shortening the length of experimentation. The latter would also avoid the risk of biotechnology products becoming irrelevant to farmers' needs due to approval delays (Atanassov *et al.* 2004). In this regard, continuous training of personnel from regulatory bodies of developing countries on new biotechnology developments and approaches is necessary for them to make educated recommendations, as is envisioned in the Cartagena Biosafety Protocol (CBD 2000). A well functioning regulatory system can hasten public acceptance of biotechnology products by instilling public confidence that the risk assessments conducted are carefully done, science-based, and, therefore, safe. While international harmonization of standards may be required, there is also need for contract-sensitivity that is appropriate to the place in which a technology will be applied (National Agricultural Biotechnology Council 2004).

Policy support. Policy initiatives are necessary to accelerate investments by technology holders and adoption by the farming communities in Asia. The Indian government, for example, is formulating new policies to boost investments and research in the local biotechnology sector. These include promoting the speedy approval of GM crops, and funding and infrastructure support for public-private partnership programmes plant biotechnology, among other areas (Sinha 2004). The new policies will also provide the framework for research and business institutions, and illustrate the trade and investment guidelines for the newly emerging biotech sector. A group of experts will also be set up to suggest models for public-private partnerships in the biotech sector. The biotechnology department will invest the creation of innovation centers with the existing academic and research institutions (Bhan 2004). To date, Delhi University has been identified to be the first center to receive the funding. Other cities such as Hyderabad, Pune, Chennai, Ahmedabad, and Lucknow will also be the focus of the development. Similarly, in Taiwan, Premier Yu Shyi-kun pledged his commitment to establish a Biotech Industry Strategy Consulting Committee, which would consolidate and integrate the country's biotech-based promotion organizations and research institutes (Crop Biotech Update 2004c).

Aside from policy initiatives, transparent protocols must also be established and international guidelines followed. There is also the need to establish a world-class intellectual property rights regime for biotechnology inventions and the protection of plant varieties. In addition, concurrent and transparent trials for biosafety for both new and released events are necessary and a determined drive against illegal genetically modified seeds trade is important.

Biosafety and food safety. Biotechnology is a very powerful tool that can be used in the developing world to grow more rice in an environmentally friendly manner. It can improve food production by making farming more efficient. The benefits that biotechnology confers upon the environment include the reduction in the use of agrochemicals and the preservation of presently uncultivated and marginal lands and their concomitant biodiversity due to increases in productivity in the more favorable environments. To sustain the rice agriculture resource base and avoid environmental disturbance, it is important to match new genes and biotechnology-derived varieties to the conditions of the target environments (Atanassov *et al.* 2004). As commercialized GM crops by 2003 in the developing world was largely limited to insect-protected cotton in Argentina, China, India, Mexico, and South Africa (James 2003), there is still limited experience on food safety assessments to draw from for a food crop such as rice. Among developing countries, only three have approved a single transgenic event in a food crop (soybean in Brazil, Czech Republic and Uruguay; and maize in the Philippines), two have approved two events (soybean and tomato in Mexico; soybean and maize in South Africa) and one (Korea) has approved three events (one in soybean and two in maize) (Atanassov *et al.* 2004). Therefore, the sharing of experiences and knowledge from the food safety assessments done in these countries should be valuable for developing countries with rice biotechnology products in the pre-commercialization stages. As rice is a food crop, and per capita rice consumption could vary both in-country and among countries, from less than 100 kg/yr in countries like China and India to over a 200 kg/year in countries like Myanmar (Maclean *et al.* 2002), careful food safety experimentation must be done in the case of nutrient-enhanced GM rice to remove potential health dangers related to over dosages, if any, or alternatively, effective GM rice deployment strategies need to be developed.

Communication. Communication plays a vital role in disseminating information. It is a powerful tool in influencing man's decision. Media plays a crucial role in framing public understanding of science. Appreciation of traditional knowledge is essential for science to be communicated successfully. The message will be understood and better appreciated if there is an understanding of local knowledge (Luganda 2004). It is important to understand cultural values, and respect traditional knowledge to successfully communicate science. Scientists, journalists and others involved in the communication of science should take into account cultural factors and local knowledge in their work (Public Communication of Science and Technology, 2004). The adoption and use of biotechnology and genomics should be approached within the context of conventional practices. Rather than view agricultural biotechnology as the wave of the future, we should regard it as part of a mélange of the new and old, balanced appropriately to meet local needs. The point was emphasized that agricultural biotechnology would be more readily adopted, and food security would be more attainable as would environmental sustainability, if it were blended back into conventional practices in order that value-added benefits would accrue alongside maintenance of traditions (NABC 2004).

There are good examples of public education campaigns on biotechnology being done in Asian NARES. In Thailand, the Biotechnology Alliance Association (BAA) has been set up to educate the public about biotechnology applications, including genetically modified crops. Science based information will be provided to the public and several fora will be organized to discuss the benefits and risks of GM crops so that stakeholders can make intelligent decisions relative to biotechnology and its use (Sriwantanapongse 2004). The potential for biotechnology to result in economic environmental, and social benefits in India is enormous and p omotion of the country's first hand experience in this area, through knowledge sharing activities, could serve as a powerful example for other developing countries (ISAAA 2004). In the Philippines, the Biotechnology Association of the Philippines along with the Departments of Agriculture and Science and Technology, have also been mounting information campaigns through public dialogues, media presentations and regular press releases.

Given all these issues and challenges, lessons can be learned from the saga of Golden Rice™ as to the merging of factors necessary for a rice biotechnology product to be developed and commercialized for impact. As detailed by Potrykus (2000), the project was made possible because of the enabling factors such as: (i) environment supportive of independent research; (ii) strong institutional collaborative research partnerships; (iii) availability of the needed genes; (iv) support from donor institutions for strategic research for developing countries; and (v) highly motivated team of scientists willing to work on a pro-poor R&D agenda. He further noted that the Golden Rice™ experience should: (i) facilitate greater public acceptance of GMO technology; (ii) encourage research investments in projects without guarantees for success, (iii) motivate research to be more food security- and less industry-focused; (iv) encourage free licensing for enabling technologies if used for humanitarian purposes; and (v) motivate scientists to undertake projects relevant to the poor.

Conclusion

The application of biotechnology in rice will help many Asian NARES to produce the estimated 700 million tonnes of rice required to feed an additional 650 million rice consumers by 2025. At the same time, it can also help lower the cost of rice farming, and add nutritional value to rice, thus benefiting resource-poor farmers through higher incomes and improved nutrition and health. Moreover, biotechnology may also be harnessed to protect the environment and sustain the natural resource base. The technology, however, must continue to draw its relevance from its being able to address both the existing and projected problems of small rice farming communities and, at the same time, the food and health needs of more than half of the world's population that consumes rice. Furthermore, products must be so designed such that they complement rather than replace existing practices and enrich rather than disrupt the agroenviroments for which they are targeted for deployment. Integration of new science with traditional knowledge would be important in this regard. For the full potential of rice biotechnology to be realized in Asian NARES, the full engagement of and sustained effective communication amongst all stakeholders, at all levels, in the public, private, NGO, and other relevant sectors of society are needed. In these, Asian governments can play a catalytic role by developing responsive programmes and policies to ensure that the benefits of rice biotechnology applications will impact poor farmers and consumers, through a stable household food and economic security, and sustainable rice-based farming systems.

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Biotechnology and Rice: The Challenges Ahead

Devinder Sharma*

Thirty-eight years after the Food and Agriculture Organisation of the United Nations (FAO) first celebrated in 1966 the International Rice Year, rice is once again in crisis. As the International Year of Rice 2004 draws to an end, it is time to understand how the world's most important staple food has undergone a complete metamorphosis – to emerge from the shadows of mankind's heritage to a profit-raking commercial and private property. In this paper, we will examine the new and emerging threats that are beginning to take away the shine from rice cultivation.

Staple food for more than half the world's population, rice is known to be an essential part of the Asian culture, rice is the unstated religion of Asia, and in essence rice is the life of Asia. It is in Asia still that more than 97 per cent of the world's rice is grown. Nearly 91 per cent of world's rice is produced in Asia, and 92 per cent is eaten in Asia. Rice is the principal food of three of the world's four most populous nations: People's Republic of China, India and Indonesia. For more than 2.5 billion people in these three countries alone – rice is what they grow up with. For centuries, rice has been the sociology, tradition and lifeline for the majority world.[1]

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In early part of the last century, rice was freely available for farmers, consumers and the scientists. Freely available means that it came without any IPR controls. The green revolution period was such an example when rice varieties were being freely available and cultivated. It was not free of cost but means there were no restrictions on its availability. Whether it were the 200,000 plant accessions of rice that were known to be cultivated some 200 years ago or the handful of dwarf and high-yielding rice varieties and its numerous national variants the world over that have led the march against hunger in the recent past, rice was a realm of nature.

As the celebrations commemorating the International Year of Rice 2004 come to an end, a leading multinational agribusiness giant, Syngenta, has already claimed ownership of rice.[2] In other words, biological inheritance of the world's major food crop is now in the hands of a Swiss multinational. The journey of rice, beginning with the emergence of wild rice some 130 million years ago, transcending through the Himalayas, passing through southern China, hopping to Japan, travelling to Africa, traded to Middle East and the Mediterranean, shipped to Mexico and America has finally ended at the banks of river Rhine in Basel, Switzerland under the monopoly control of Syngenta.[3]

When reports first appeared about the mapping of the rice genome, agricultural scientists were excited. After all, the mapping of the rice genome – the genetic map of the rice plant — appears to be a vital tool for boosting yields and relieving world hunger. And for agriculture scientists and policy makers, this is obviously a cause for cheer. How relevant is the genomic research in the fight against hunger is something that we need to carefully assess.

FAO officials have been quoted as saying that the technological breakthrough "will provide us an additional tool to increase food production in the next 20 years as the population rises," adding, "food could become more affordable to the poor people who consume it." The International Rice Research Institute (IRRI) says that the world's rice-eating population is growing faster than rice output and investment is urgently needed to teach poor families to boost rice yields. The growth rate of rice yields dropped to one per cent a year in the 1990s from around 2.5 per cent a year in the 1970s and 1980s.

These data, however, do not reveal the real truth. The alarm that the scientists raise runs contrary to the global trade regime that force opens the Asian agriculture to cheaper rice imports thereby destroying food self-sufficiency that many of the big developing countries had so assiduously built. If increasing rice productivity and thereby rice production is the challenge for the future there seems to be no justification in allowing the agribusiness giants in the western countries to flood the domestic rice markets in the developing countries with rice.

Agriculture scientists and economists are, however, quite when it comes to international trade. On the other hand, a false alarm is being raised so as to create a favourable atmosphere for the agribusiness industry (read biotechnology companies) to set roots thereby ensure livelihood security of scientists already faced with declining investments in public sector research. Let us see how.

Produce and Perish

It remains a fact that the rice yields in the South Asian countries, including India, are amongst the lowest in the world. In India, for instance, if we were to exclude the rice productivity in Punjab, Haryana, Andhra Pradesh and Tamil Nadu, the average yields of rice paddy hovers around three tonnes a hectare. This is lower than the high rate of productivity exceeding six tonnes a hectare in China and seven tonnes in USA. So even without incorporating the 'cutting-edge' technology, genetic engineering, there exists tremendous scope to multiply production (at least by three times) by simply improving the management of the crop farming systems; for example, in Punjab, the rice paddy productivity is over five tonnes per hectare. In China, it is six tonnes per hectare. This means that productivity in the low production areas can also be increased substantially with the existing technology. All we need is the right policy mix that does not allow cheaper food to be imported thereby destroying the livelihood security of the rice growers in the first instance.

Some years back, at the height of the paddy harvesting season in 2000, hundreds of thousands of farmers in the frontline agricultural states of Punjab, Haryana and western Uttar Pradesh, in northwest India, had waited for three weeks before the government agencies were forced to purchase the excess stocks. For weeks, farmers sat patiently over heaps of paddy in the grain markets. At least 25 farmers, unable to bear the economic burden that comes with crop cultivation, preferred to commit suicide by drinking pesticides. In Andhra Pradesh, in south India, there were no buyers for the five million tonnes of paddy surplus. Even in the poverty-stricken belt of Bihar and Orissa, in north-central

India, farmers waited endlessly for the buyers as a result rice farmers in these states are not being provided procurement facilities as a result of which they have to resort to distress sale.

Farmer's suicide is perhaps a reflection on the breakdown of institutional safety nets, which in the past have cushioned the impact of agrarian crisis. Farmers are increasingly becoming victims of a new emerging phenomenon 'produce and perish', which has extended its grip to countries as far as Indonesia where rice farmers wait in vain for the buyers while the country finds it cheaper to import low quality rice from Vietnam. Moreover, farmers can no longer turn to banks and credit societies for loans and procurement support; the public distribution system no longer offers food supplies at substantially subsidized prices; and market intervention is only partial – a combination of frustrating circumstances.

India's ranking in productivity brings it to the bottom of the chart, with per hectare yield or productivity hovering amongst the lowest five or ten countries. The conclusion therefore can be that increasing productivity will bring more income to farmers and thereby increase their presence and competitiveness in the international market.

Take the case of rice, the most important staple food crop of India. In the year 2000, India's rice paddy yield was hovering at 3008 kg per hectare. In Thailand, the major rice exporter, paddy productivity stands at 2329 kg. In the United States, the average yield per hectare was more than double at 7037 kg. If productivity alone was the criteria, the US should have captured the entire world market in rice. And at the same time, Thailand shouldn't have been able to export rice considering that its average productivity is lower than even India. But that did not happen. Thailand continues to be the biggest exporter of rice.

Moreover, even with such low rice paddy productivity, India had a record procurement of 20.9 million tonnes of rice in the 2001-02 marketing season. The grain stock build-up over the last few years has seen India's rice and wheat surplus increase to an unmanageable level of 51.4 million tonnes in October 2002 (against a record 65 million tonnes in June 2001) In fact, chief ministers of surplus rice producing states of Punjab, Haryana, and Andhra Pradesh have been repeatedly asking their farmers not to produce more of rice as they have no place to stock it. The Indian government too has been toying with the idea of getting out of food procurement leaving farmers to the vagaries of the market.

In the United States, however, despite the high paddy productivity, farmers find its cultivation uneconomical. The US government, therefore, continues to subsidize the American farmers. Estimates point that the American farmers receive an average subsidy of US $ 30,000 per farm per year. As if this is not enough, the notorious Farm Bill 2002 provides an additional federal support of US $ 180 billion for the next ten years. If high productivity is the criteria for global competitiveness, there is no plausible reason why the American farmers would depend upon government doles for survival.

To ask the Indian farmers, therefore, to increase paddy productivity is to merely push them into a death trap. Already, rice farmers in Punjab and Andhra Pradesh continue to suffer for producing more. For the past two years, with the Food Corporation of India (FCI) refusing to buy paddy under one pretext or the other, distress sale has become a common phenomenon. At many a places, a number of rice farmers preferred to commit suicide waiting endlessly for buyers in the markets. The scenario for wheat producers is no different. They too are faced with the 'produce and perish' syndrome.

Indonesia was rated among the top ten exporters of rice before the World Trade Organization (WTO) came into effect. Three years later, in 1998, Indonesia had emerged as the world's largest importer of rice.[4] Rice imports in Sri Lanka have doubled between 1985 and 1998. All major and small rice producing countries are faced with the threat of cheaper imports. Increasing productivity at a time when these countries are unable to encounter any check on stalling the subsidies imports (following the unjust rules being framed by the WTO) therefore runs contrary to the warnings that FAO keeps on issuing at regular intervals.[5]

It is generally believed that technology alone can't make a difference. It was a combination of appropriate public policies, and the right kind of infrastructure, that made the miracle of green revolution possible. In India and elsewhere, the productivity gain in rice was accompanied by assured prices to farmers by way of support prices and the government stepped in to mop up the rice surpluses flowing into the markets at the time of harvest. In short, providing an assured price and an assured market galvanized rice farmers to produce more. But these planks of the 'famine-avoidance' strategy that have helped countries like India and China emerge from the throes of hunger and starvation are now being withdrawn.

Manipulation Control

Agribusiness giants kept on arguing with the scientific community that crops like rice, wheat and other cereals are of no commercial interest to them. Their focus was on cash crops like strawberries, cut flowers, tomatoes and the likes, which could rake in big profits. This prompted universities, which developed such technologies in the first place, to license these to the private corporations. Knowing well that patenting alone will determine who wields power over farming and world food system, a tug of war began over who controls the rice plant genome – the raw sequences in the genetic code.

The tussle over the monopoly control of rice extends to its 12 chromosomes. These chromosomes contain 430 million base pairs of DNA, and are expected to have about 50,000 genes. Syngenta, in collaboration with Myriad Genetics Inc of USA, has beaten Monsanto in the game by sequencing more than 99.5 per cent of the rice genome. Syngenta has already made it clear that it will restrict access to the genomic map and expects proprietary control over any research carried out with the information.

Top executives of Syngenta have already told the *New York Times* that while the companies would not seek to patent the entire genome, they would try to patent individual valuable genes as global harmonization of patent regime continues. They categorically stated that Syngenta and Myriad were well on their way to finding many of those. First Monsanto, which made international headlines in April 2000, for announcing to share its working draft (rougher, 60 per cent) of the genome map with international researchers sequencing the rice genome under a publicly funded International Rice Genome Sequencing Project (IRGSP), and then Syngenta making it clear of the efforts to seek patents on genes with visible commercial output, the race is on to draw proprietary control over something that existed in nature.

There are conflicting reports of the latest tally of patents over rice genes. Some researchers say that more than 900 genes have already been patented. Earlier, GRAIN had compiled a list of 609 patents on rice genes drawn till Sept 2000, 56 per cent of which were owned by private companies and research institutes in the western countries. Top of the list was the American giant Du Pont with 95 patents, followed by Mitsui, Japan, with 45 patents. In the next three years, especially after the mapping of the rice genome by Syngenta, a majority of the patents would surely be in the lap of a handful of multinational agribusiness companies.

The Consultative Group on International Agricultural Research (CGIAR), which governs the 16 international agricultural research centers for public good, has actually welcomed the recent developments in rice. In fact, the CGIAR has even gone a step ahead by taking Syngenta on board – thereby ensuring that the company gets a free access to the world's biggest rice germplasm collections that it has. It is known that IRRI has the world's biggest collection of rice germaplsm. IRRI was so far a public funded research institute. By now taking Syngenta as one of its members, Syngenta will now have direct access to the plant germplasm of IRRI. This makes all the material transfer agreements redundant.

The quest for control over rice does not end with patenting of its genes. In 2002, stung by criticism, Syngenta India had to pull out from the controversial research collaboration with the Indira Gandhi Agricultural University (IGAU) at Raipur. The collaboration would have given the company commercial rights to over 19,000 strains of local rice cultivars held by the university. These rice varieties were painstakingly gathered by the agricultural scientist R H Richharia in the 1970s. In exchange, the university would have received an undisclosed amount of money and royalties. What is also relatively unknown is the fact that the Richharia rice collections were not the only plant species that the company had an eye for. It has reportedly gone into numerous agricultural universities in India, singing agreements that enable the company commercial rights over the hybrid rice varieties in lieu of five per cent royalties from sales.

Syngenta gained exclusive rights on the controversial Golden Rice technology in exchange for help with the IPR issues and the different testing of the rice for a humanitarian project. This happened when the international community was negotiating an agreement to see that the 70-odd patents that were coming in the way of free transfer and application of the technology were removed. Ingo Potrykus, university professor of the Swiss Federal Institute of Technology, who developed the Golden Rice, was in a desperate haste to see that his name is enshrined in history as the saviour of the malnourished.

The patent was applied a year later, naming Igno Potrykus and his colleague Beyer as the inventors, and facilitating an agreement with Zeneca, now Syngenta. For the Swiss company, the IPR over Golden Rice provides a human face to its manipulative gene control designs. The company has already announced that the technology will be free for farmers in the developing countries with annual incomes of less than US $ 10,000, a wonderful exercise in public relations knowing well that the Golden Rice has little utility and relevance for the developing countries. These rice lines are now being withdrawn. The Indian Council of Agricultural Research has already directed the research institutes to stop using these transgenic rice strains.[6]

Hidden Hunger

The much-touted 'golden rice', the rice that contains the genes for beta-carotene, is another scientific folly that is being promoted in the name of eradicating 'hidden hunger'. Let us see what in reality it aims at. It is true that there are 12 million people in India alone who suffer from Vitamin A deficiency. It is also known that almost the entire Vitamin A deficient population in India lives in marginalized areas and comprise people who cannot or who do not have access to two square meals a day. If only the e hungry people were to get their adequate dietary intake or the two square meals a day, they would not suffer from Vitamin A deficiency or for that matter any other micro-nutrient deficiency. If these poor people cannot afford to buy their normal dietary requirement of rice for a day, how do we propose to make available 'golden rice' to them is something that has been deliberately left unanswered.

In India, which is technically speaking "self-sufficient" in food grain production, reports of hunger and starvation pour in regularly from the infamous Kalahandi region and more recently from Kashipur in Orissa on the eastern coast. The region, with a population of 20 million, suffers from the pangs of hunger and malnutrition despite any visible signs of ecological devastation. These are the areas where majority of the people who suffer from Vitamin A deficiency live.

The problem is certainly not of production. What is not well known is that the Kalahandi region is the biggest contributor of surplus rice to the central food reserves. Between 1996 and 2001, Kalahandi provided some 50,000 tonnes of rice surplus on an average to the food reserves of the government of India. Kalahandi is the area where the marginalized wait endlessly for the rice that rots in front of their eyes in government godowns. The reason why people die of starvation and hunger is not because there is not enough food, but because they cannot afford to buy the food they produce. Biotechnology has no mechanism to ensure that food comes within the reach of these poorest of the poor. To say that 'golden rice' would provide the poor with a choice of such 'novel foods' is to ignore the realities.

To say "if the developing community turns its back on the explosion of technological innovation in food, it risks marginalizing itself," is in reality a desperate effort to ensure that the corporate interests are not sacrificed at the altar of development. Such is the growing desperation at the growing isolation of the genetically engineered food industry because of its `transgenic' food that all kinds of permutations and combinations, including increased food-aid to Africa's school-going children and force-feeding the hungry populations in southern Africa, are being attempted.

Biotechnology, it is said offers the only or the best "tool of choice" for marginal ecological zones — left behind by the green revolution but home to more than half the world's poorest, dependent on agriculture and livestock. It is true that the green revolution left behind the small and marginal farmers living in some of the world's most inhospitable areas. But the way the tools of the cutting-edge technology are being applied and are being blindly promoted, it is obvious that the interests are not altruistic.

The reality of hunger and malnutrition is too harsh to be even properly understood. Hunger cannot be removed by producing transgenic crops with genes for beta-carotene. Hunger cannot be addressed by providing mobile phones to the rural communities. Nor can it be eradicated by providing the poor and hungry with an "informed choice" of novel foods. In its over-enthusiasm to promote an expensive technology at the cost of the poor, what has been overlooked is that biotechnology has the potential to further the great divide between the haves and have-nots. What has been forgotten in the first instance is that unless hunger is removed, 'hidden hunger' cannot be eradicated. In other words, if the global scientific and development community were to aim at eradicating hunger at the first place, there would be little "hidden hunger".[7]

Rice farmers in India or for that matter in other developing countries have the capacity and the capability to fight hunger and 'hidden hunger' provided they are given an enabling environment.

Endnotes

[1] *Down to Earth*, 2004.

[2] This is clear from the material transfer agreement that Syngenta has put up.

[3] Down to Earth, 2004

[4] Oxfam International 2002.

[5] Sharma, 2003.

[6] Sahai, 2004.

[7] This incorporates some sections from the author's earlier writings on the subject, mainly from the article "Rice is now Oryza sativa".

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Emerging Trends in Managing and Using Rice Genetic Resources

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Rice genetic resources comprise traditional farmers' varieties, landraces, commercial cultivars, hybrids and other elite materials developed through plant breeding and biotechnology. They also include wild progenitors and wild relatives of rice that could be used for either agriculture or environmental benefits. These resources form the primary building blocks that provide the much needed genetic variation for all the rice improvement work undertaken by the breeders, biotechnologists and other researchers. Conservation of genetic resources is about preservation and use. For further evolution of germplasm there is a need to continue growing the resources in their natural *in situ* conditions with suitable backup through long term storage in gene banks under *ex situ* conditions. Recent advances in biotechnology and development of new molecular techniques hold promise for improving efficiency of managing the germplasm collections (stored in gene banks at high costs) by detecting duplicates and aiming possibly at true gene banks storing DNA segments/nucleotide sequences in place of seed samples, supported by more efficient computerised documentation systems. They will also promote the greater use of stored collections by more precise characterization of inventories

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at the molecular level, facilitating allelic diversification along with location of loci on genome maps responsible for the desired quantitative traits based on marker-assisted approach. Accordingly, the role of modern gene bank managers has expanded considerably and forms the focus of this paper.

Seventh meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD), held in Kuala Lumpur in March 2004, emphasized the linkage between biological diversity, food (and nutrition) security and sustainable agriculture. With the International Treaty on Plant Genetic Resources for Food and Agriculture entering into force on June 29, 2004, major crops are back in the multilateral domain along with access and benefit sharing and Farmers' Rights. Bonn Guidelines on Access and Benefit Sharing provide a framework for action for developing further clarity on responsibilities and procedures related to access to germplasm. India is well placed to play a lead role in the emerging scenario because of its strong national plant germplasm system which is comparable to the best in the developed world. India's Biological Diversity Act 2002 has been enacted to meet national commitments under provisions of CBD providing access to its genetic resources under multilateral system (based on material transfer agreements) while claiming sovereign rights over them (exercised through the National Biodiversity Authority). The Protection of Plant Varieties and Farmers' Rights Act 2000 is an effective *sui generis* national legislation, patterned largely on the provisions of UPOV 1978, that protects both the breeders' and farmers' rights relevant to terms under the WTO-TRIPS agreement. Detailed information on these two legislative measures are available at the websites maintained by the Government of India.[1]

Domestication of Rice and Centres of Its Diversity

There are two cultivated species of rice, viz., *Oryza sativa* (widely known as the Asian cultivated rice including the two ecospecies *indica* and *japonica*) and *O. glaberrima* (called the African cultivated rice). Both are diploid species with chromosome number 2n = 24. The former is believed to have been domesticated in south and southeast Asia and it is widely cultivated throughout all the rice growing areas of the world. Wild rice species *O. rufipogon* (a perennial species) and *O. nivara* (an annual relative), growing naturally in several parts of India and many other adjacent areas, are considered to be its putative progenitors. The African cultivated rice appears to have originated in tropical West Africa from the wild rice species O. *barthii* and its cultivation is almost confined to that region.

India is considered as one of the centers of origin of rice (*Oryza sativa* ssp. indica) and an important centre of its diversity (Ramiah, 1953; Richharia, 1960; Chang, 1976). Rice is the staple food for its large population and this crop is cultivated in almost all the Indian states under a remarkably wide range of agro-climatic conditions and ecological situations. The Jeypore tract in Orissa in particular displays striking variability in a large array of traits and growth characteristics as described in details by Richharia and Govindswami (1966) and Rao (1991). This tract has been proposed to be the likely area where indica rice was domesticated (Sharma *et al.* 1997). Traditional practices of managing and developing this vast wealth of genetic diversity by farming families within rice-based cropping systems should form an important part of the strategy for *in situ* on-farm conservation and sustainable use of rice genetic resources.

Aforementioned, diversity at the genetic level within cultivars, landraces and closely related wild forms of rice is crucial for providing resilience against biotic, abiotic and climatic stresses. Accordingly, germplasm representing the diversity observed in cultivated and wild forms is collected by the breeders to access and make use of the desired traits. Gene banks further enrich such collections through planned explorations and store the collected seed samples under medium and long term storage after duly processing them. This kind of *ex situ* conservation of germplasm collections in gene banks also provides reliable backup to on-farm *in situ* conservation against unforeseen calamities while ensuring at the same time easy and instant availability of these materials to plant breeders and other researchers whenever needed. Nearly 200,000 seed samples of cultivated and wild rice forms have already been kept under long term storage in national and international gene banks (See Table 1 for information on major collections).

Rice Genetic Resources

Major components of rice genetic resources are:

- Vast genetic diversity available in the cultivated Asian and African rices, developed and conserved by farming families over the past ten millennia or even more.

Table 1: Some Major Ex Situ Collections of Rice Genetic Resources

Gene Bank / Organisation	No. of Accessions Stored under Long Term Storage	Remarks
Indian National Gene Bank,National Bureau of Plant Genetic Resources, New Delhi.	66,858	Includes nearly 700 samples of wild rice forms.
International Rice Gene Bank, Genetic Resources Center, IRRI, CGIAR, Philippines.	96,261	Includes 4,370 samples of wild rice forms. In addition, over 10,000 samples are under processing.
National Plant Germplasm System, USDA-ARS, USA.	21,292	Includes 382 samples of wild rice forms.

- Twenty-two wild species of rice still growing and evolving in Asia, Africa, Australia, and the Americas. Only six of them are closely related to the cultigens. See Tables 2 and 3 for further information.
- Eleven other genera in the tribe *Oryzeae* are distantly related to rice and some of their species, such as *Porteresia coarctata* having tolerance to saline conditions, are being investigated for their value in rice breeding, through the application of biotechnology.

Role of the Gene Bank Manager/Curator

Gene banks are *ex situ* biodiversity reservoirs and sources of alleles for sustainable genetic enhancement of plant crops. Collecting plant germplasm along with passport information, through carefully planned explorations and exchange, is an important activity of the Gene Bank manager. Collections of plant breeders and relevant organizations are also pooled at the national level. Seed samples collected from the farmers along with related information are held in-trust with the expectation that these will be eventually returned to them in due course in the form of improved new varieties recognizing Farmers' Rights (for getting their varieties protected and for planting as well as non-labeled-marketing of seeds, also their products, harvested by them from their crop and also claiming compensation where due).

The collected seed samples are tested for their viability and health and then given an identity/accession numbers. This is followed by phenotypic and biochemical characterization and also some preliminary agronomic assessment along with resistance screening against pests and diseases. Seed or propagule regeneration and multiplication of

Table 2: Taxonomic Relationships in Rice (*Oryza* species) 2 Cultivated and 22 wild species

Species	Chromosome No. (2n)	Genome
O. barthii	24	AA
O. glumaepatula	24	AA
O. longistaminata	24	AA
O. meridionalis	24	AA
O. nivara	24	AA
O. rufipogon	24	AA
O. glaberrima ———Cultivated	24	AA
O. sativa ————Cultivated	24	AA
O. alta	48	CCDD
O. eichingeri	24, 48	CC
O. grandiglumis	48	CCDD
O. latifolia	48	CCDD
O. minuta	48	BBCC
O. officinalis	24, 48	CC
O. punctata	24, 48	BB, BBCC
O. rhizomatis	24	CC
O. australiensis	24	EE
O. brachyantha	24	FF
O.granulata	24	GG
O. meyeriana	24	GG
O. neocaledonica	24	GG
O. longiglumis	48	HHJJ
O. ridleyi	48	HHJJ
O. schlechteri	48	HHKK

Source: Lu Bao-Rong, *et al.* (2002).

recalcitrant crops is also a routine activity despite the costs involved in maintaining *in vitro* collection. They are grown in the field for seed multiplication along with characterization, based on approved descriptors, and documentation and multiplication. The resulting information is pooled in the national database network. Appropriate catalogues are prepared and shared with *bona fide* users (breeders and researchers). Both the aforementioned legislations make suitable distinction among Indian nationals, non-resident Indians and foreigners. Information on nodal authorities for signing Material Transfer Agreements, based on prior informed consent and mutually agreed terms, is available on the above mentioned websites.

For the medium term storage, seed samples are checked for seed health and viability, dried to around 5 per cent moisture content and then packaged in paper bags or laminated aluminum foils or other suitable containers before storing them at 5° C and 35 to 40 per cent RH. For the long term storage, the seed samples (containing around 3

Table 3: Description of the Putative Wild Progenitors of Cultivated Asian Rice (*Oryza* sativa) and Cultivated African Rice (*Oryza glaberrima*)

Description	Asian Rice Domesticated in South and Southeast Asia		African Rice Tropical West Africa
Characteristics	*Oryza rufipogon*	*Oryza nivara*	*Oryza barthii*
Habit	Perennial, tufted, and scrambling grass with nodal tillering; plant height variable (1-5 m) depending on the depth of water; panicles open.	Annual, short to intermediate height (usually <2 m) grass; panicles usually compact, rarely open.	Annual and erect to semi-erect grass; leaves with short ligule (<13 mm); panicles compact to open, rarely having secondary branching.
Chromosome Number	2n=2x=24	2n=2x=24	2n=2x=24
Genome	AA	AA	AA
Distribution	Asia (Australia, Bangladesh, China, India, Indonesia, Laos, Malaysia, Myanmar, Nepal, Papua New Guinea, Philippines, Sri Lanka, Thailand, and Vietnam)	Asia (Bangladesh, Cambodia, China, India, Laos, Malaysia, Myanmar, Nepal, Sri Lanka, Thailand, and Vietnam)	Africa (Benin, Botswana, Burkina Faso, Cameroon, Central Africa Republic, Chad, Côte d'Ivoire, Ethiopia, The Gambia, Ghana, Guinea, Mali, Mauritania, Namibia, Niger, Nigeria, Senegal, Sierra Leone, Sudan, Tanzania, and Zambia)
Habitat	Found in open ditches, swampy grassland, at the edges of lakes, and in or at the margins of rice fields. Grows in clay/loam soil and black soil.	Found in swampy areas, at edge of pond and tanks, beside streams, in ditches, in or around rice fields. Grows in shallow water up to 0.3 m, in seasonally dry and open habitats.	Found in savanna. Grows in deep water, seasonally flooded land, stagnant water, and slowly flowing water or pools; prefers clay or black cotton soils. Found in open habitats.

Source: Lu Bao-Rong, *et al.* (2002).

to 4 thousand seeds each), sealed in laminated aluminum foils, are stored at (-) 20°C in specially designed modules. Seed viability is checked at regular intervals and the samples showing more than permissible reduction in viability are sent for regeneration to the designated sites that take due care for the samples' genetic integrity. Relevant gene bank standards are also strictly adhered to.

Adequate capacity for taxonomic identification and quarantine inspection are essential requirements for such facilities. Gene banks are also equipped with modern computerized database with specialized software to suit the requirements including networking.

The gene bank manager/curator acts as the trusted link between the seed providers and users of the germplasm collections. He arranges maintenance of national active germpasm collections for important crops at suitable sites in partnership with capable institutes/ organizations encouraging easy access to users through field visits.

Adding Value to Germplasm Collections

A proper documentation system is the key to effective utilization of a gene bank's resources. Faster and more reliable computers allow researchers to manage and analyze data more easily, and publish catalogues and reports. Gene bank characterization and documentation have been also significantly enhanced with advances in information technology, geographical information systems (GIS) and DNA marker technology. Computerized documentation systems, and information provided by GIS or from DNA assessment of variation, can help plant explorers in searching for specific sites where specific desirable genes may be found. Well-documented analysis of the number and types of useful polymorphism allows gene bank curators to offer specific accessions with the desired characteristics to research geneticists or plant breeders, who can then select material tailored to their needs (IPGRI, 2002: De Vincente, 2004).

In situ On-Farm Conservation of Genetic Resources

Gene banks should promote *in situ* conservation to maintain the genetic integrity of plant populations in their natural sites promoting their evolutionary development. Likewise, gene banks should support on-farm management and improvement of plant genetic resources in partnership with the farmers. This evolutionary conservation approach also continuing natural selection in diverse environments, and has low direct costs. It also increases people's control over their genetic resources. Rational *in situ* conservation can help in supporting the co-evolutionary dynamics between crops and wild relatives, and the pathogen populations of each species.

Accession Duplicates and Safety Duplication of the Collections

Duplicated accessions within a collection must be identified to avoid waste of costs and capacity. Probable duplicates can be identified on the basis of passport data, but additional assessment/confirmation is needed using descriptor lists in the field and biochemical or DNA marker testing in the laboratory. It is considered important to provide for safety duplication for the main germplasm holding at another suitable site to safeguard against unforeseen calamities and accidental losses.

Core Collections Concept

Some gene banks have large and diffuse germplasm collections, which are often ineffectively managed and seldom accessed by plant breeders. Assessment of genetic diversity in these collections helps in developing core collections that help in improving both the management and also the utilization of the collection. Core collections are subsets of the main collection, comprising selective accessions that represent most of the genetic variability contained in the entire collection. The main collection can be stratified into groups (subsets) sharing common characteristics according to taxonomy, geographic or ecological origin, and descriptors, followed by sampling within these groups. A core subset provides in a way an entry point to the entire collection for accelerating the utilization of germplasm and should not be looked upon as a substitute of the latter.

Advent of Biotechnology Molecular Techniques

Agricultural biotechnology has recently emerged as a priority research area in India with the expectation that it may help in developing novel, value added products and useful tools. It holds the potential to increase and stabilize food production, reduce the dependency on chemicals, and lower the cost of raw materials, all in an environmentally friendly manner (See Table 4 for relevant information). Major research topics include:

- Mapping and sequencing of agriculturally important plant/animal/microbial genomes to elucidate gene function and regulation with a view to facilitating desired genetic modifications.

Table 4: Agriculture and Biotechnology Application

Period	Notable Developments
Around 10,000 BC	Beginnings of agriculture. Civilisations, harvesting from natural biological resources, begin domesticating crop plants and animals while practising selection of desirable plant materials for propagation and animals for breeding.
Late 19th Century	Discovery of the principles of inheritance by Gregor Mendel in 1865 and subsequent rediscovery around 1900, laying the foundation for classical breeding methods.
1930s	Development of commercial hybrid maize.
1940s to 1960s	Application of induced polyploidy, mutagenesis, tissue culture and plant regeneration. Discovery of transformation and transduction. Double helix model by Watson and Crick in 1953 for the structure of DNA.
1970s	Advent of gene transfer through recombinant DNA techniques. Use of embryo rescue and protoplast fusion in plant breeding and artificial insemination in animal reproduction.
1980s	Tissue culture for mass propagation in plants and embryo transfer in animal production.
1990s	Genetic fingerprinting of a wide range of organisms. First field trials of genetically engineered plant varieties in 1990 followed by the first commercial release in 1992. Genetically engineered vaccines and hormones and cloning of animals.
Around 2000 onward	Bioinformatics, genomics extending to proteomics and metabolomics

Source:. The State of Food and Agriculture. FAO, 2004.

- Studying genetic control along with biochemical/molecular basis of metabolic pathways, growth and development to assist in developing new products with novel food, pharmaceutical, and industrial uses.
- Understanding the molecular basis of interactions of plants and animals with their physical and biological environments to improve genetic adaptation to stress environments.
- Strengthening food safety assurance methodologies including rapid tests for identifying chemical and biological contaminants in food and water.

Genetic markers and DNA banking

Molecular markers are descriptors that offer reproducible results for characterizing genotypes. Applied plant genomics also improves the understanding of crop gene pools. This gene pools concept has been enlarged by including transgenes and "native" gene pools. Molecular markers and gene sequencing are important tools for gene bank management, particularly because they can be used to estimate genetic relationships within a germplasm collection (IPGRI, 2003). Unique materials can be preserved or collection gaps identified with the aid of DNA markers, which can be used to properly assess genetic diversity (IRRI, 2002: Hamilton, 2004). Moreover, DNA markers provide an alternative means of monitoring and facilitating the introgression of genes from wild species into cultivated gene pools.

Sequencing of crop genomes has opened new frontiers in biodiversity conservation and genetic enhancement (Yu, 2002). Advances in gene isolation and sequencing in plant species offer the possibility that within a few years, gene bank curators could replace their large cold stores of seeds with crop DNA sequences, which will be electronically stored and easily accessed by users.

This characterization of plant genomes will create true gene banks, which should possess a large and accessible gene inventory of today's non-characterized crop gene pools (Richards, 2004). Of course, seed banks of comprehensively investigated stocks should remain because geneticists and plant breeders — the main users of gene banks — will need this germplasm for their work.

Finding new genes adds value to traditional agricultural products. Genetic resources available in gene banks are still the best source for an easy gene discovery. This work will be facilitated by gene databases assembled with the aid of applied plant genomics, which can also accelerate the utilization of available genes through transformation or meiotic-based breeding methods.

Genetic and Molecular Mapping of the Rice Genome

A fairly detailed genetic map of rice has been developed covering all the 12 linkage groups contributing to our understanding of the structure, function and evolution of the rice genome. The linkage map contains valuable information for the rice breeders showing the relative locations of specific genes along the chromosome. Any inherited physical or molecular characteristic that differs among individuals and is easily detectable is a potential genetic marker. Markers can be expressed DNA regions (genes) or DNA segments that have no known coding function but whose inheritance pattern can be followed. DNA sequence differences are especially useful markers because they are plentiful and easy to characterize precisely. Markers must be polymorphic to be useful in mapping; that is, alternative forms (alleles) must exist among individuals so that they are detectable among different members in the mapping population. Table 5 provides more information on additional desirable characteristics of molecular-genetic markers. The plant genomic effort is challenging since the range of plant genome size is very large extending from approximately the same size as the genome of many small animals to more than five times as large as the human genome. While the construction of detailed gene-linkage maps of complex genomes facilitates the localization of genes to specific regions on chromosomes, more precise allocation of specific genes requires cloning of high-molecular-weight DNA if it is to be done efficiently (De Vincente, 2004). Subsequently, information contained in the gene map and the molecular map needs to be verified and integrated.

Table 5: Desirable Properties of Useful Molecular-Genetic Markers

Properties	Remarks
1. Highly polymorphic	Should be variable among individuals. The degree of polymorphism detected depends on the technology used to measure it.
2. Reproducible	Reproducible in any laboratory experiment, whether within experimental events in the same laboratory or between different laboratories performing identical experiments.
3. Codominant	Depending on the type of application, the selected technology must be able to detect the marker's different forms, distinguishing between homozygotes and heterozygotes (codominant inheritance). A heterozygousindividual shows simultaneously the combined genotype of the two homozygousparents.
4. Evenly distributed throughout the genome	The more distributed and dense genome coverage is, the better the assessment of polymorphism.
5. Discriminating	Should be able to detect differences between closely related individuals.
6. Not subject to environmental influences	The inference of a marker's genotype should be independent of the environment in which the individual lives or its developmental stage.
7. Neutral	The allele present at the marker locus is independent of, and has no effect on, the selection pressure exerted on the individual.
8. Inexpensive	Easy, fast and cheap in detecting across numerous individuals. If possible, the equipment should be of multipurpose use in the experiment.
9. Easy to measure	

Source: IPGRI, 2002.

Detailed information on genome maps for 34 organisms, including 8 plants (Rice, Wheat, Maize, Barley, Oat, Soybean, Tomato and Thale Cress), are now available representing both completely sequenced organisms and those for which sequencing is in progress (See NCBI Website for more information). These developments have opened new vistas in characterization and classification of gene bank holdings and detect duplicates. There are publicly as well as commercially funded efforts to sequence the rice genome. There are two publicly funded rice genomic sequence projects. One, the International Rice Genome Sequencing Project, undertaken in 1997, is a collaboration of publicly funded investigators working to sequence the *Oryza sativa specie japonica genome*. The second effort, initiated in April 2000, is the whole-genome shotgun sequencing project sponsored and funded by the Chinese Academy of Sciences; Beijing, China. This project reported a draft sequence assembly of *Oryza sativa specie indica* in the April 5, 2002 issue of Science (Yu and the Team members, 2002).

The first commercial effort, by Monsanto, resulted in a database of genomic sequence that has been shared with the International Rice Genome Sequencing Project members. The second commercial effort, collaboration between Myriad Genetics and Syngenta, used the whole-genome shotgun method. However, a press release in January 2001 noting the completion of the "rice genome map" by this project notwithstanding, little genomic sequence has been deposited into the public domain.

Candidate Genes Identification and Transfer

A major goal of plant genome research is to develop and implement strategies for the isolation of genes for desirable agronomic traits such as disease resistance. To begin with, there is need to isolate individual rice chromosomes and to make chromosome-specific gene libraries (one of each of the 12 chromosomes). After the completion of this work, it would be relatively easy to clone the different resistance-conferring genes from domestic as well as wild rice species (IRRI, 2002). The bacterial blight of rice is an attractive system for studies on disease resistance because both the host and pathogen are amenable to molecular genetics.

Although remarkable progress has been made in resistance breeding without the knowledge of what resistance genes do; isolation of a plant disease resistance gene may ultimately lead to novel and environmentally safe methods of disease control. The relatively small genome, large fraction of low copy DNA and transformability of rice makes this crop a model monocot for such studies. Hence, yield losses due to stress environment can be avoided by developing rice varieties disease resistant (against viral, fungal and bacterial related diseases), and insect tolerant (against different insect pests). The gene coding for many of these traits are present in different wild rice species. It would be very important to locate and characterize these genes by screening germplasm collections systematically, first by physical mapping and then by cloning.

Gene Bank accessions with high frequency of important heritable traits need to be identified and subjected to Restriction Fragment Length Polymorphism (RFLP) mapping techniques to further define the locations of specific genes. It will be desirable to develop methods to identify genetically controlled characteristics, such as grain quality, and develop probes to expedite gene transfer among varieties. Construction of a rice library containing short tandem repeat sequences will be required, along with precise information on verified correlations between workable markers, for targeting the transfer of marker-assisted Quantitative Trait Loci (QTL).

Cost of Genetic Resources Conservation

The danger of excessive reliance by farmers and breeders on a narrowing genetic base was dramatically revealed by the widespread infestation of US hybrid corn (having cytoplasm male sterility) with southern corn leaf blight in the early 1970s. This incidence renewed worldwide effort to expand the amount of agricultural biodiversity conserved *ex situ* in gene banks for use in crop breeding. Over six million samples of seed and other propagules are now stored in about 1300 gene banks worldwide at enormous costs. Modern biotechnologies, providing new and less costly ways of screening crop samples for useful traits, have increased the usefulness of genebanks to breeders.

The storage costs of seed samples at IRRI and ICARDA gene banks (average around US$0.47 per accession per year for crops kept at both locations) are comparatively low because of the cheap labour and electricity costs, whereas these costs are higher at ICRISAT (US$1.32 per accession), where electricity is expensive (Koo *et al.*, 2003). Conservation cost, including both recurrent and non-recurrent components, per accession per year in the Indian National Gene Bank varies around US$ 0.77 (Singh and Saxena, 2004). Long term conservation cost (including periodic viability testing and regeneration costs) of wild rice at IRRI is about US$68.76 per accession and that of chickpeas at ICRISAT comes to nearly US$15.48 per accession, respectively) because of the higher costs of repeated regeneration (See: Koo *et al.*, 2003). conserving *in vitro* costs US$11.98 per accession per year. As a rule, wild and weedy varieties, cross-pollinating crops, and vegetatively propagated crops, that are relatively expensive to regenerate, are more costly to conserve over the long term. Distribution costs are substantially higher than the conservation cost in present-value terms because of the more frequent viability testing and the additional regeneration costs associated with medium-term storage.

Multilateral Trade and Environment Agreements

Release of genetically modified organisms (GMOs) and genetically engineered crop varieties ushered in a new era of highly contested developments relevant to safeguarding the environment and also the centres of origin and diversity of crop plants. The genetic use restriction technology (GURT) sought to enable the multinational seed companies to develop such high yielding varieties of self-pollinated crops like wheat that would prevent the farmers from using the seed of their own crop for sowing in the following season. The government of India responded promptly by banning the import of such products in India.

Provisions under Trade-Related Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) made it obligatory for the member countries in 1995 to protect plant breeders' rights by enacting suitable national legislation for this purpose or through an effective *sui generis* system of plant variety protection. India's Protection of Plant Varieties and Farmers' Rights Act 2000 sought to meet this obligation.

Entry into force of the Convention on Biological Diversity (CBD) on 29th December, 1993 was another significant event since this Convention recognized for the first time the sovereign rights of nation states over their natural biological resources and also on setting terms of access to them based on prior informed consent ensuring equitable and fair sharing of benefits. This replaced the earlier notion adopted by the FAO (Through the Commission on Plant Genetic Resources), viz., that plant genetic resources were the common heritage of humankind. Cartegena Protocol on Biosafety was subsequently adopted by the CBD to regulate the movement of GMOs and pursue related matters. India is actively participating in the follow-up negotiations including the precautionary principle and polluter to pay provisions. India has enacted Biodiversity Act 2002 responding to obligations under the CBD.

Issues concerning agricultural biodiversity in general; and plant genetic resources (PGR) in particular, have attracted priority attention in the agenda of successive meetings of the Conference of Parties to CBD. Two items related to PGR were referred to the FAO for perusal, viz., the status of designated germplasm collections held in International Gene Banks under the CGIAR system and the decision regarding germplasm collections made/transferred prior to the CBD. The FAO-CPGR responded by suitably revising the content of the International Understanding on PGR in harmony with provisions of the CBD. These prolonged negotiations led to the International Treaty on PGR that entered into force on 29th June 2004 bringing the genetic resources of 35 food crops and 29 forages back into the public domain for common access through multilateral system to ensure food and nutrition security.

There is some apparent overlapping and even inconsistency in the provisions of the aforementioned two legislations and it is expected that the implementation rules being framed for them would take care to reconcile them.

The Way Ahead: New Role of Gene Bank Managers/Curators

It is paradoxical that the countries, that are considered the centers of origin and diversity of major food crops including rice, happen to be lagging behind in development as may be observed among the Group of 17 Biodiversity Diverse countries spread across the globe. This is so when these countries have unmatched reservoirs of naturally occurring plant genetic resources and many of them have also developed large gene banks. A common constraint appears to be lower application of recent advances in biotechnology and molecular biology for want of access and adequate funding. There is indeed a large scope for technical cooperation and technology transfer at regional and international levels (See: IPGRI, 2002; Raney and Pingali, 2004).

A noteworthy development in this context is the beginning of a positive dialogue in recent years between the enthusiastic supporters of biodiversity conservation movement and the advocates of sustainable development opening up vast avenues of meaningful interactions and moving forward. Indian economy is essentially agro-based and, hence, sustainable development in India is inseparably linked to sustainable agriculture pointing out the urgency of taking up more comprehensive strategies and programmes of diversifying agriculture (Rana, 2004). The crop improvement projects, underway in different agro-ecosystems and varying agroclimatic conditions, will have to play a key role in achieving this objective and they will have to draw more and more from the germplasm collections held in gene banks employing new biotechnology and molecular techniques.

Following this approach, the gene bank managers will henceforth be required to cater to the needs of biotechnologists and molecular biologists in addition to breeders and other researchers (De Vincente, 2004). They will also be required to solicit active involvement of specialists in these fields for accelerating the characterization of germplasm collections, screening against molecular markers for disease resistance and QTL, and identification, isolation, cloning and transfer of candidate genes in rice and other major crops (SGRP, 1999; IPGRI, 2002; Richards, 2004; Hamilton, 2004; IRRI, 2004). Development of reliable databases, updated through new information technology, will facilitate access of relevant data to all *bona fide* users (IPGRI, 2003, Dhillon *et al.* 2004).

A fast emerging role for the gene bank managers and PGR workers relates to IPR issues and the development of workable Material Transfer Agreements (and also their implementation through active follow up actions) vis-a vis the implementation of the provisions of various genetic resources-related agreements and international treaties. Additional responsibilities will include registration of elite genetic stocks/developed germplasm and storing referral seed samples of all the varieties released for commercial cultivation. Introduction of genetically engineered crop varieties and GMOs will also demand more compelling attention. Considering that the seed samples along with passport information were obtained from the farmers of different part of the country in trust, the gene bank manager/curator has the obligation towards promoting Farmers' Rights to their resources, knowledge, technology choices and production systems as protected under the Protection of Plant Varieties and Farmers' Rights Act 2000.

India is a Contracting Party to many international treaties related to biodiversity, environment and trade that have apparently conflicting provisions and require harmonization (Bragdon, 2004). In addition, there are two recently enacted national legislations with direct bearing upon access to genetic resources and benefit sharing implications. These aspects require not only the effective coordination at the highest level among different national nodal points with overlapping responsibilities but also convergence of policy decisions of relevant Union Ministries and State Governments.

Costs are steadily rising for collecting germplasm samples, growing them for seed multiplication, characterizing and documenting them, processing seeds for storage, packaging and storing them for long term, monitoring their viability and regenerating them when due. Estimated costs vary across gene banks from less than 1 to over 15 US$ per accession per year (See: Koo *et al.*, 2003). Since conservation, characterization, documentation of plant genetic resources and their supply to all *bona fide* users is a national responsibility for the NBPGR, there is need for committing funds for this purpose on a long term basis and making appropriate budgetary allocation, both at the national and state levels.

Developing and acquiring new biotechnology tools and molecular biology techniques are costly propositions for the developing countries and also require additional infrastructure and capacity building. Scope and feasibility of regional and multilateral technical cooperation, provided under terms of various biodiversity-related international agreements/conventions, need to be explored with greater urgency to assist the desired technology transfer and also capacity building in developing countries.

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Biosafety Considerations for Genetically Engineered Rice

Lim Li Ching*

Introduction

Rice feeds more than half of the world's population. In much of Asia, rice is the staple food. The highest producing countries of rice are in Asia; in 2003, China produced 166,417,000 Mt (metric tonnes) of rice paddy, India produced 132,013,000 Mt and Indonesia produced 52,078,832 Mt (FAOSTAT 2004).

Agricultural biotechnology has been developing at a rapid pace, and genetic engineering has been proposed as a means of improving various aspects of crop production. Rice has been no exception, and developing countries have been urged to facilitate the adoption of genetically engineered (GE) rice (Datta 2004).

Adoption of GE rice in Asia, particularly China, is seen as potentially demonstrating the benefits of genetic engineering and reducing opposition to it (Brookes and Barfoot 2004. China, the world's largest producer and consumer of rice, is reportedly on finalising the commercialization of the same (Jia 2004; Lei 2004). Chinese scientists have been researching GE rice since the 1980s. Research is also being conducted in other Asian countries, including Japan, India, the Philippines and Thailand.

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Despite the apparent positive outlook for GE rice, concerns have been raised in respect of its impact on the environment, human and animal health, and socio-economic situations (e.g. Cummins 2004; Stabinsky and Cotter 2004a, 2004b).

In particular, it appears that GE rice research has thus far, outpaced biosafety considerations. The Assistant Director-General for Asia-Pacific of the Food and Agriculture Organization of the United Nations (FAO), He Changchui, has been quoted as saying that Asian governments should move cautiously before approving commercial planting of GE rice (Mohanty 2004). He urged governments to undertake extensive risk assessment on food safety.

This paper examines some of the biosafety issues that will need to be considered before any commercialization of GE rice.

Research on GE rice

This section briefly and selectively highlights some of the research conducted on GE rice. Traits reportedly closest to commercialization are glyphosate and glufosinate tolerance, resistance to bacterial leaf blight (using the *Xa21* gene), and resistance to Lepidopteran insects (using Bt toxins) (Brookes and Barfoot 2004).

Herbicide tolerance

Aventis (formerly AgrEvo) has developed GE rice tolerant to the herbicide glufosinate ammonium. Two events, LLRICE06 and LLRICE62, are no longer considered regulated items in the U.S. and can be grown commercially (APHIS 1999). These GE rice have not been commercially grown yet, presumably due to the lack of markets. Bayer, which bought over Aventis, is currently seeking approval for the import of LLRICE62 for food, feed and industrial uses into the European Union (Bayer 2003). Monsanto is developing GE rice tolerant to the herbicide glyphosate, and has reportedly conducted field trials in Japan and the U.S. (Brookes and Barfoot 2004). Scientists have expressed various human cytochrome genes in GE rice, to confer tolerance to the sulphonylurea herbicides (Inui *et al.* 2001).

Insect resistance

The Cry toxin genes from the bacterium *Bacillus thuringiensis* (Bt) code for several insecticidal Bt toxins; these have been introduced into rice to protect against Lepidopteran pests, particularly yellow stem borer (*Scirpophaga incertulas*), striped stem borer (*Chilo suppressalis*) and rice leaf folder (*Cnaphalocrocis medinalis*) (Khanna and Raina 2002; Ye *et al.* 2001; Ye *et al.* 2003). The most frequently used Cry toxin genes are *Cry1Ab* and/or *Cry1Ac* genes (High *et al.* 2004).

Plant protease inhibitors like the cowpea trypsin inhibitor (CpTI) inhibit plant protein digestion in insects. The CpTI gene has been introduced into rice to protect against striped stem borer and pink stem borer (*Sesamia inferens*) (Xu *et al.* 1996).

GE rice with the snowdrop lectin *Galanthus nivalis* agglutinin (GNA) gene resists sap-sucking insects, such as the small brown planthopper (*Laodelphax striatellus*) (Sun *et al.* 2002). GE rice expressing three insecticidal genes (Bt genes *Cry1Ac* and *Cry2A*, and *gna*) provided protection against rice leaf folder, yellow stem borer and brown planthopper (*Nilaparvata lugens*) (Maqbool *et al.* 2001).

Disease resistance

Bacterial blight is caused by the bacterium *Xanthomonas oryzae* pv. *oryzae* (*Xoo*). The rice gene *Xa21* provides wide-spectrum resistance against *Xoo*, although the endogenous gene is expressed at low levels. Genetically engineering rice by inserting *Xa21* enhances bacterial blight resistance. *Xa21* has been pyramided (combining genes by conventional crossing) with a fused *Cry1Ab/Cry1Ac* gene to confer resistance to insects and bacterial blight (Jiang *et al.* 2004). Two transgenic lines, one with *Xa21*, the other with a rice chitinase gene for protection against sheath blight and a synthetic gene with fused *Cry1Ab/Cry1Ac*, were pyramided to resist bacterial blight, yellow stem borer and sheath blight (Datta *et al.* 2002).

Rice blast is caused by the fungus *Pyricularia oryzae.* A gene from a medicinal herb, *Trichosanthes kirilowii* expressed the protein trichosanthin in GE rice, delaying blast infection (Ming *et al.* 2000). Rice chitinase genes and maize genes triggering anthocyanin (a flavonoid pigment) production can also confer blast resistance (Brookes and Barfoot 2004; Gandikota *et al.* 2001).

Research on virus resistant GE rice includes resistance to rice yellow mottle virus (RYMV), rice hoja blanca virus (RHBV), rice tungro spherical virus (RTSV) and rice ragged stunt virus (RRSV) (Brookes and Barfoot 2004).

Tolerance to abiotic stress

GE rice has been developed to tolerate low iron availability in alkaline soils (Takahashi *et al.* 2001). Over-expressing a rice sodium antiporter (a pump that moves sodium ion) gene improved salt tolerance (Fukuda *et* *al.* 2004). Manipulating plant polyamine biosynthesis produced drought-tolerant rice (Capell *et al.* 2004) and the barley gene *Hva1* inserted into rice reduced drought damage (Babu *et al.* 2004).

Nutritional enhancement

Scientists have expressed provitamin A (beta-carotene) in rice grains, creating 'Golden Rice' (Ye *et al.* 2000), promoted as a cure for vitamin A deficiency (e.g. Potrykus 2003). GE rice rich in iron has been developed to combat iron deficiency anaemia. Insertion of a ferritin (an iron storage protein) gene from the bean *Phaseolus vulgaris* increased iron content up to twofold (Lucca *et al.* 2002).

Production of pharmaceuticals

Rice has been genetically engineered to produce pharmaceutical products. Field trials of GE rice that produce the human milk proteins lactoferrin, lysozyme and alpha-1-antitrypsin have been conducted in California since 1997 (Freese *et al.* 2004). In 2004 Ventria Bioscience proposed starting commercial cultivation of biopharmaceutical rice, but has been blocked by the authorities, for now.

Biosafety Considerations

There is a wide range of GE rice under development, offering potential benefits. However, all GE rice must undergo risk assessment. This section points to some general potential environmental health and socio-economic impacts of GE rice.

Environmental concerns

Asia is the centre of origin for the genus *Oryza*. There are wild relatives of rice, known to hybridize with cultivated rice, and weedy relatives (e.g. red rice). Gene flow via outcrossing or cross-pollination is inevitable as the necessary spatial, temporal and biological conditions are met in many Asian rice-producing areas (Lu *et al.* 2003). Although outcrossing rates may be low as rice is largely self-pollinating, "given the vast area over which rice is cultivated and wild and weedy rices occur, transgenes will almost certainly escape into non-transgenic plants" (High *et al.* 2004).

Gene flow between cultivated rice (*O. sativa*) and the widely distributed wild rice *O. rufipogon* was shown to occur considerably under natural conditions (Lu *et al.* 2003). Gene flow was demonstrated with a noticeable frequency from cultivated rice to its weedy (~0.011-0.046 per cent) and wild (~1.21-2.19 per cent) relatives (Chen *et al.* 2004).

Weedy rice is already a problem in more than 50 countries in Asia, Africa and Latin America, reducing rice yield and quality. Traits such as herbicide tolerance, insect, virus and disease resistance, and abiotic stress tolerance, if acquired from GE rice by wild and weedy relatives, could significantly enhance their ecological fitness. One possible consequence is the creation of more aggressive weeds, with resulting unpredictable damage to local ecosystems. Chen *et al.* (2004) recommend that GE rice should not be released, when it has transgenes that can significantly enhance the ecological fitness of weedy rice or that confer herbicide tolerance, in regions where weedy rice is already abundant and causing problems.

Hybrids of GE rice and wild relatives could swamp populations of wild species, possibly leading to their extinction and impacting agrobiodiversity. Crop genetic diversity is important for food security, acting as a reservoir for future breeding efforts. As Asia is the centre of origin of rice, any release of GE rice there must be mindful of this fact. Traditional varieties of maize in Mexico, a centre of origin and diversity of maize, have already been contaminated by transgenes (CEC 2004; Quist and Chapela 2001). The Commission for Environmental Cooperation of North America (CEC) (2004) recommends strictly enforcing the current moratorium on commercial GE maize planting in Mexico.

Gene flow through horizontal gene transfer (HGT; no parent-to-offspring transfer of genes) from GE rice to soil microorganisms is an area of omitted research. However, studies have shown that HGT between GE plants and microbes occurs under certain conditions (Nielsen *et al.* 1998). Significantly, methods for monitoring HGT from GE crops to microbes are problematic and too insensitive to detect HGT (Heinemann and Traavik 2004; Neilsen and Townsend 2004). As such, even though monitoring so far has largely failed to observe HGT events in the field or has deemed frequencies too low or too rare to pose risks, claims that HGT is not a significant risk are not justified.

Widespread adoption of herbicide tolerant GE rice could lead to problems in the long-term. In the U.S., where GE crops have been planted commercially for nine years, pesticide use has increased overall (Benbrook 2004). This was primarily due to an increase in herbicide usage, largely because there has been a shift towards more herbicide tolerant weed species or the development of weeds resistant to herbicides, particularly glyphosate. This has led farmers to spray incrementally more herbicides, and ultimately would require the usage of more toxic herbicides.

The impacts of GE rice on biodiversity have yet to be adequately researched. Some herbicide tolerant crops (GE oilseed rape and beet) have significant effects on biodiversity (FSE 2003). Weed densities and biomass, and abundance of some invertebrates, were found to be lower in GE crops than in conventional controls.

Insects may eventually evolve resistance to insect resistant GE rice. If this happens, GE rice will no longer be effective at controlling insect pests and more harmful insecticides could be used instead. It is widely assumed that resistance to Bt crops will occur (Snow *et al.* 2004). In the U.S., there are strict requirements for planting Bt refuges (areas of non-Bt crops) to delay build-up of resistance. Such refuges may not be enforceable or practical on small farms like those in Asia, making insect resistance a real concern. It is also known that insects can adapt to protease inhibitors (Jongsma and Bolter 1997), so the effectiveness of CpTI in GE rice might be short-lived. Fungi, bacteria and viruses may also evolve resistance to GE rice resistant to them.

GE rice could impact non-target organisms (that are not direct targets of pest control), including beneficial species like natural enemies of pests (e.g. lacewings) and pollinators. Bt toxins have the potential to directly kill non-target insects (e.g. Losey *et al.* 1999). While pollen levels needs to be sufficiently high to cause acute toxicity, chronic effects at lower pollen levels cannot be dismissed. Tritrophic studies have shown increased mortality of non-target predatory lacewings when predating on herbivore insects feeding on Bt toxins and Bt plants (Hilbeck 2001). The effects of CpTI and GNA on non-target organisms have not been investigated fully yet and there is little experience with these GE crops. There is also little research on ecological consequences; as ecosystems are complex, impacts on one organism could have significant impacts elsewhere in the ecosystem (Snow *et al.* 2004).

Effects on soil biodiversity have not been adequately assessed. Bt toxin is released into the soil from roots and can accumulate in the soil, implying that soil organisms can be exposed to the toxin over a long time (Saxena *et al.* 2002). There are indications that earthworms are affected when fed Bt maize litter, after 200 days, the earthworms experienced significant weight loss (Zwahlen *et al.* 2003). Studies have identified changes in important biological activities when Bt rice straw was incorporated in water-flooded soils, indicating a probable shift in microbial populations or in metabolic activities (Wu *et al.* 2004).

Health concerns

It is now internationally recognised that genetic engineering can cause unintended effects, e.g. by the Codex Alimentarius Commission (joint WHO/FAO agency), which deals with the international regulation of food safety. Codex principles and guidelines related to risk analysis and food safety assessment of GE food (Codex 2003), adopted in 2003, clearly oblige an analysis of unintended effects, by requiring a case-by-case pre-market safety assessment that includes an evaluation of both direct and unintended effects that could result from gene insertion (Haslberger 2003).

Unintended effects can result from the random insertion of DNA sequences into the plant genome, which may disrupt or silence genes, activate silent genes, or modify gene expression. Insertion of transgenic DNA is often imprecise, and associated with significant rearrangement and/or loss of plant genomic DNA, as well as multiple copies, multiple insertion sites, multiple insertion of parts of the event and insertion of extraneous material, e.g. from the vector (Collonier *et al.* 2003; Wilson *et al.* 2004).

In all commercial GE plants that have been carefully analyzed so far, the transgenic inserts found in the plants are rearranged compared to the sequences first notified to regulators (Collonier *et al.* 2003). The nature of the rearrangements includes deletion, recombination, and tandem or inverted repeats. Moreover, rearranged fragments of the insert can be scattered in the genome. Some of the rearrangements involve the cauliflower mosaic virus (CaMV) 35S promoter, which has a recombination hotspot (Kohli *et al.* 1999). The CaMV promoter, used in some GE rice, may also carry specific risks (Cummins *et al.* 2000; Ho *et al.* 1999, 2000a, 2000b).

Recombination may occur between plasmids before or during transformation, or between plasmid and genomic DNA during or *after* transformation. Transgenic inserts appear to show a preference for mobile genetic elements such as retrotransposons and repeated sequences. Transgene insertions into, or close to, such elements may lead to altered spatial and temporal expression patterns of genes nearby. All this may have unpredictable effects on the long-term genetic stability of the GE plants, and on their nutritional value, allergenicity and toxicology.

As rice is a staple food in Asia, thorough risk assessments must be done on GE rice. The most relevant testing for unintended effects is a well-designed feeding trial of adequate duration, conducted using the actual GE plant or product (not bacterial surrogate products, as currently accepted by regulators). In spite of the obvious need, few studies investigating the effects of GE food/feed on animals or humans have been published in peer-reviewed journals (Domingo 2000). Most animal feeding studies conducted so far have been designed to show husbandry production differences between GE and non-GE crops. The few studies that have been designed to reveal physiological or pathological differences demonstrate a worrying trend (Pryme and Lembcke 2003): Studies conducted by industry find no differences, while studies by independent researchers show differences that merit immediate follow-up.

For example, young rats fed GE potatoes expressing GNA showed changes in their gastrointestinal tract (Ewen and Pusztai 1999). Crypt length in their jejunums was significantly greater. The findings are similar to research describing fine structural changes in the small intestine of mice fed Bt potatoes (Fares and El-Sayed 1998). In addition, the number of cells in the crypt and the mitotic rate (number of cells dividing) increased in the jejunum of rats fed GNA potatoes (Pusztai *et al.* 2003). The implications for GE rice with GNA or Bt toxins have not been explored.

The liver of mice fed glyphosate tolerant GE soya underwent significant modifications of some morphological features (Malatesta *et al.* 2002). The liver had irregularly-shaped nuclei, more nuclear pores and more irregular nucleoli, suggestive of increased metabolic rate. However, the mechanisms responsible remain unknown. Glyphosate tolerant GE rice should be investigated for such effects.

Other health concerns include toxicity and allergenicity of transgenic products. One particular aspect of GE rice is that fused, stacked or pyramided genes are increasingly used, although the full health implications have yet to be considered. At the very least, the toxicity of *each* transgenic toxin, *and* the combinations of toxins, must be risk assessed (Cummins 2004). Nutritionally enhanced GE rice also needs to be evaluated fully, as changes are being made directly to nutritional content.

Many transgenic proteins contain sequence similarities to known allergenic proteins (Kleter and Peijnenburg 2002), a first indication of potential allergenicity. Notably, Bt protoxin Cry1Ac, expressed in some GE rice lines, is a potent systemic and mucosal immunogen (invokes immune response) (Moreno-Fierros *et al.* 2000; Vázquez-Padrón *et al.* 1999). Immune response should be further investigated for being indicative of a potential allergic response.

The persistence and fate of DNA and proteins from GE crops have not been extensively studied. However, *in vivo* studies showed that Bt protein (Cry1Ab), as well as transgenic DNA from Bt maize (fragments of *Cry1Ab* gene), survived digestion in the gut of pigs (Chowdhury *et al.* 2003). Others found that a 1914-bp DNA fragment containing the entire coding region of the synthetic *Cry1Ab* gene was amplifiable from sheep rumen fluid sampled 5 hours after feeding maize grains and "may provide a source of transforming DNA in the rumen" (Dugan *et al.* 2003:159).

If transgenic DNA survives digestion, it may be available for HGT to gut bacteria. This could possibly create new disease-causing viruses and bacteria, and spread antibiotic resistance marker genes (ARMGs) to pathogenic bacteria, making infections harder to treat (Ho 2004). The use of ARMGs in many GE rice lines is a concern. European legislation (Directive 2001/18/EC) mandates the phase out of ARMGs in GE crops, particularly if they are in medical or veterinary use. In the only human study, research showed that transgenic DNA can survive digestion in the human stomach and small intestine, and provided evidence of pre-existing horizontal gene transfer from GE soya to gut bacteria (Netherwood *et al.* 2004).

GE rice producing pharmaceuticals is intended for use by drug companies or in industrial processes, and not for consumption. The compounds are often biologically active chemicals and are potentially toxic. Pharmaceutical production should not be conducted in food crops because of the high risk of contamination (Editorial 2004). Contamination could occur via gene flow, grain admixture or human error. In 2002, soybean and non-GE maize were contaminated with GE maize engineered to produce an experimental pig vaccine (APHIS 2002). The CEC (2004) recommends that maize genetically engineered to produce pharmaceuticals and industrial compounds should be prohibited in Mexico and that a similar ban should be considered in other countries; the same should apply to GE biopharmaceutical rice.

Socio-economic concerns

Rice is much more than a vital food crop; it is also culturally, religiously and socially embedded in many societies. For example, the Balinese have cultivated a diversity of traditional varieties of rice for religious ceremonies. *Subak* organizations, comprising rice farmers in adjacent fields, collectively irrigate the rice terraces. They also make decisions on all aspects of rice production, including of offerings at the small temple each *subak* has in the fields. These practices embody an agri-*culture*, intricately linking rice production with religion, culture and social relations. The potential contamination of traditional varieties of rice with transgenes from GE rice would be an affront to peoples for whom rice is, literally, life itself.

Contamination of non-GE rice could also jeopardize people's right to choose non-GE and could affect export markets. Some degree of cross-pollination of non-GE rice is almost inevitable. GE rice previously planted in the same field and seed in the soil seed bank could germinate at a later date, contaminating non-GE rice. Seed saving and seed exchange, common practices in Asia, and spillage during transport, could also lead to inadvertent spread of GE rice.

Another issue to consider is that of intellectual property rights (IPRs) over GE rice. Many patents on rice genes have been lodged; in 2001, 240 patents had been granted on rice, 60.8 per cent of which were corporate-owned (Madeley 2001). Patented GE rice owned by corporations would take control of rice out of the hands of local farming communities. Should patented GE rice contaminate non-GE rice, the implications for farmers who traditionally save and exchange seeds are unclear.

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Rice Research in India and the Asian Perspective

R. C. Saxena* and R. K. Singh**

Rice, *Oryza sativa,* is the staff of life for the population in Asia, particularly in South and Southeast Asia where more than 90 per cent of rice is produced and consumed. It is also a major source of livelihood for more than 250 million households. Providing adequate food entitlements, safeguarding public health, and at the same time preventing deforestation and conserving the environment are daunting challenges in the new millennium for countries in Asia, especially India where the population has already crossed the billion mark. Rice is the major source of calorie intake and also contributes to the total agricultural income in most of the Asian countries. World-wide, rice is grown over 153.766 M ha (Maclean *et al.* 2002). In Asia, rice is grown in 136.642M ha. India has the largest area (44.6M ha) under rice in the world and is second only to China in terms of rice production. It is the staple food of 65 per cent of the total population in India. It constitutes ca. 52 per cent of the total food grain production and 55 per cent of total cereal production.

Over the pasts three decades, the advent of modern high yielding rice varieties and associated Green Revolution technologies have almost doubled the rice production in South and Southeast Asia. Several

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countries in the region have not only achieved self-sufficiency in rice production, but also a few of them, including India, have become net exporters of rice. However, with the growing population, the demand for rice will also continue to grow. A challenge in the future would be that more rice would have to be produced from less land, with less water, less labour, and lesser use of pesticides. This would require innovative research and technologies and policies that promote increased rice production. Here we analyse the current status of rice production and review the constraints, opportunities and advances in rice research and developments as well as some emerging concerns to meet the targeted production of rice in South Asia, especially India.

Rice Demand and Supply Scenario

With increasing population and increasing incomes the demand for rice will continue to grow in coming decades. The population of South Asia, which was about 1.1 b in 1990, is expected to increase at a rate of 1.8 per cent and reach 1.9B by 2020 (Rosegrant *et al.* 1995). In spite of a slightly slower population growth rate of 1.7 per cent, the population in India will cross the 1.3B mark by 2020 and might overtake the population of China by 2035. Consequently, the demand for rice will grow and, hence the production must also increase. In 1990, the total rice production in South Asia was 101M tonnes and the demand was 99M tonnes, leaving a surplus of 2M tonnes. By 2020, rice production is projected at 197.62M tonnes as against a demand of 197.59M tonnes. Thus, rice production and demand will almost be balanced in contrast to a surplus of 2M tonnes in 1990 (Table 1). This could be attributed to somewhat a reduced rate of production growth, especially in Pakistan and Bangladesh. Although India and Pakistan will have a marginal surplus, but if the total factor productivity decelerates, they could also face a deficit in rice supply. For Bangladesh, a deficit of about 1 to 2M tonnes has been predicted by 2010 (Shahabuddin 2000). If the rate of growth in rice production is not sustained at the predicted levels, then the gaps between demand and supply could increase to 3M to 6M tonnes. On the whole, the rate of growth in production will be slower than the rate of growth in demand. Also, the demand for growth rate of rice in South Asia will be higher than the average rate projected for developing countries as a whole.

The per capita calorie intake in South Asia will improve from 2297 kilo-calorie in 1990 to 2640 kilo-calorie in 2020. Therefore, during that

Table 1. Projected population, demand and net supply of rice in South Asia , Southeast Asia and the world for 1990 to 2020

Country/ region	1990					2020					Growthrate	
	Area ('000 ha)	Yield (mt/ ha)	Production ('000 mt)	Demand ('000 mt)	Net supply ('000 mt)	Area ('000 ha)	Yield (mt/ ha)	Production ('000 mt)	Demand ('000 mt)	Net supply ('000 mt)	Production ('000 mt)	Demand ('000 mt)
India	42,321	1,781	75,388	74,758	630	44,237	3,293	145,777	144,792	985	2.22	2.23
Pakistan	2,594	1,329	3,448	2,101	1,347	2,918	2,127	6,207	5,309	898	1.98	3.14
Bangladesh	10,303	1,814	18,689	18,115	574	10,944	3,479	38,204	38,204	-132	2.40	2.52
Other S A countries	2,161	1,807	3,905	4,341	-436	2,244	3,369	7,561	9,283	-1,721	2.23	2.57
South Asia (total)	57,379	1,768	101,430	99,315	2,115	60,380	3,273	197,617	197,588	29	2.25	2.32
SE Asia	36,976	1,954	72,268	67,594	4,386	39,680	3,217	127,647	116,125	11,523	1.91	1.82
Asia (excluding Japan)	129,70	12,418	313,602	307,425	5,889	134,875	3,770	508,452	495.332	13,119	1.62	1.60
Developed world	4,280	4,075	17,440	17,376	64	4,412	5,107	22,534	20,135	2,399	0.86	0.49
Developing world	142,139	2,336	332,026	332,090	-64	150,629	3,609	543,616	546,016	-2,399	1.66	1.67
World (total)	146,419	2,378	349,466	349,466	-1	155,041	3,652	566,150	566,150	0	1.62	1.62

Table 2. Food availability, percentage, and number of malnourished children

Country/ region	Kcal/ capita/ day		Malnourished (%)		Malnourished (no.)	
	1990	2020	1990	2020	1990	2020
India	2,332	2,692	63.0	45.5	70,858	47,728
Pakistan	2,370	2,584	41.6	32.1	9,128	9,899
Bangladesh	1,978	2,170	65.8	52.3	11,963	11,456
Other South Asia	2,239	2,565	37.0	26.5	2,012	2,127
South Asia	2,297	2,640	58.5	41.37	95,811	72,939
Developed countries	3,353	3,532	-	-	-	-
Developing countries	2,500	2,821	34.3	25.1	18,440	155,729
World	2,773	2,895	-	-	-	-

period, the per cent malnourished children would decline from about 58 per cent to 41 per cent. However, the total number of malnourished children will decrease only moderately from 95,811 to 72,939, with nearly all the improvement in India (Table 2). The number of malnourished children in other South Asian countries will continue to be high during the next two decades (Agcaoili-Sambilla and Rosegrant 1996).

Constraints and Opportunities

South Asia accounts for about 39 per cent of land under rice cultivation in Asia. However, due to low average yields, its share in the world rice production is less. A major factor for low rice yields in South Asia is that only 42.3 per cent of the total rice grown area is irrigated, while the remaining 57.7 per cent area is rainfed, which suffers from uncertain weather conditions and periodic droughts, resulting in low and unstable yields (Table 3). Due to risk of crop failure, application of inputs, especially fertilizer, is low in rainfed ecosystems. In India, for example, the average rate of fertilizer applied to irrigated rice is ca.170 kgNPK/ha, as compared with 32 kg NPK/ha in rainfed environments.

Erratic rainfall leading to drought during the vegetative period in uplands, or prolonged submergence during the later stage in flood-prone areas are the major yield-reducing factors. Other constraints relate to the land and soil. Coastal salinity is a problem in Bangladesh and parts of India. Sodic soils are also prevalent in India and Pakistan. Cold injury, soil erosion, and micro-nutrient deficiencies, and blast are the major constraints of rice cultivation in hilly areas of Nepal, Bhutan, and India. Deficiency of P and K, and iron toxicity are common in Bhutan, Nepal, and Sri Lanka, while Zn deficiency is prevalent throughout the region. Lack of infrastructure, leading to low inputs

Table 3. Estimated harvested irrigated (IR), rainfed lowland (RL), upland (UL), and flood-prone (FP) rice areas in South Asia

Country	IR (% of Σ rice area)	IR rice area (000 ha)	RL (% of Σ rice area)	RL area (000 ha)	UL (% of Σ rice area)	UL area (000 ha)	FP (% of Σ rice area	FP area (000 ha)
Bangladesh	24.2	2480	43.1	4415	8.6	881	24.1	2469
Bhutan	50.0	13	3.8	1	3.8	1	42.3	11
India	43.8	18685	30.1	12852	14.6	6238	11.4	4874
Nepal	23.0	325	60.6	855	3.1	44	13.3	188
Pakistan	100.0	2097	0.0	0	0.0	0	0.0	0
Sri Lanka	77.0	610	14.9	118	6.9	54	1.1	9
Total (")	42.3	24210	31.9	18241	12.6	7218	13.2	7552

Table 4. Crop loss due to rice insect pests, diseases, and weeds in various countries of South Asia

Pest (s)	Country	Crop loss
Stem borers	Bangladesh (outbreak year)	30-70%
	Bangladesh (non-outbreak year)	3-20%
	India	3-95%
Leafhoppers and planthoppers	Bangladesh (leafhoppers)	50-80%
	India (brown planthopper)	1-32%
Rice bug and gall midge (larvae)	India	10% loss in M ha
	India	12-35%
Blast	India	1% in 1960-61
Tungro	Bangladesh	40-60%
Baclerial blight	India	6-60%
Sheath blight	Sri Lanka	10% of rice tillers

and input-use efficiency, price fluctuation, and inefficient transfer of technologies are among other factors causing low yields in rainfed rice ecosystems of South Asia.

Rice crop losses due to insect pests, diseases, and weeds are estimated at 1 to 85 per cent (Table 4) (Rola and Widawsky 1998). Stem borers, brown planthopper, gundhi bug, leaffolders, green leafhopper, and gall midge are the major rice insect pests affecting large yield losses in South Asia. Bacterial leaf blight, blast, sheath blight, brown spot, and tungro are important diseases. With increases in wage rates, weeds are also becoming a factor constraining productivity and profitability in rice farming.

Throughout the region, the productivity in the irrigated ecosystem is quite high; 5 t/ha, compared with 2.3 t/ha for the rainfed lowland, 1.5 t/ha for flood-prone, and 1.1 t/ha for the uplands. Although the average rice yield in India is only 2.7 t/ha, compared with 5.8 t/ha in China, the average farm yield in states with dependable irrigation, such as Punjab, Tamil Nadu, and West Bengal, is 5.5 t/ha (Hossain 1995). In India itself, the variation in rice yield is highly correlated with the proportion of area under irrigation. However, recent developments indicate that yield growth has started to decline. The rate of deceleration in yields is higher for countries with higher cropping intensities. In South Asian region, it is true for Pakistan, but not for India and Sri Lanka, which is attributed to the increase in irrigation infrastructure and policy reforms during 1980s. In Nepal and Bangladesh, the increase

Table 5. Extent of sub-ecosystems of shallow rainfed lowland rice in eastern India

State	Shallow rainfed lowland sub-ecosystems (ha x 10)				
	Drought prone	Drought and sub-mergence prone	Favorable	Submergence prone	Total
Assam	-	-	450	442	892
Bihar	948	750	-	-	1,698
Orissa	700	500	275	268	1,743
Madhya Pradesh	2,695	-	-	-	2,695
Uttar Pradesh	784	1,100	-	-	1,884
West Bengal	660	350	300	375	1,685
Total	5,787	2,700	1,025	1,085	10,597

in growth has come from crop intensification. Degradation in soil and water quality and insect pest build-up in intensive rice-rice and rice-wheat systems are the main factors for declining productivity (Pingali *et al.* 1997).

While raising yield levels and stability are the main concerns in rainfed rice ecosystems, reversing the trends of yield decline and sustainability are major issues in the irrigated rice ecosystem. Since rainfed ecosystem occupies a large area, even a small increase in productivity there will make perceptible gains in the overall production of rice in the region. Rice ecosystem analysis in eastern India has revealed that quite a sizeable rainfed lowland area is favorable wherein irrigated rice technologies can be fitted and productivity raised substantially (Table 5). Similarly, the analysis of drought and moisture availability in drought-prone area has indicated that by selecting appropriate varieties and adjusting planting time the risk could not only be averted but the average yield could also be increased in such areas (Table 6) (Singh *et al.* 1999).

Another opportunity exists in "boro" rice cultivation. Recent studies have shown that yield can be increased by growing "boro"' rice in and around deep-water areas (where surface or groundwater is not a limitation). Over the past two decades in Bangladesh, as the 'boro' season crop gave higher and more stable yields, the "boro" rice area has fast increased while area under deep-water rice declined. These results have led to fast spread and adoption of the technology in West Bengal and other neighboring states of India, resulting in increase in overall average yields. Exploitation of "boro" season for rice has thus emerged as one of the thrust areas for achieving rice production targets

Table 6. **Moisture availability index (MAI) at different growth stages of medium and long duration rice varieties (values in parentheses indicate duration in weeks)**

Crop stage	Medium duration varieties		Long duration varieties	
	Required MAI	Available MAI	Required MAI	Available MAI
Seedling	0.75 (3)	0.99	0.75 ([illegible])	0.99
Vegetative	1.00 (5)	1.00	1.00 ([illegible])	0.99
Reproductive	1.00 (6)	0.95	1.00 (7)	0.87
Maturity	0.75 (4)	0.60	0.75 ([illegible])	0.62

in India (Siddiq 1999). But further research is needed to fully utilize the potential that it offers. Due to high profitability, the technology is spreading beyond the traditional areas of 'boro' rice cultivation, causing concerns for decline in underground water resource.

Little has been done about hill rice cultivation Due to favourable agro-climatic conditions, the yields are generally high. However, developing rice varieties tolerant to cold, blast, and iron toxicity should further raise productivity in hilly areas.

Both India and Pakistan are the traditional exporters of Basmati rice. They account for ca. 1 M tonnes of annual export. Past few years, India has also started exporting 4 to 5 M tonnes of non-Basmati rices annually. Beside Basmati, India has a wealth of small- and medium-grain non-Basmati aromatic rices. However, due to neglect and increased adoption of high yielding varieties, most of these scented rices have disappeared (Singh and Singh 1998). Through proper resource utilization, not only these rices could be saved from extinction, but they could also become an invaluable source of income to rice farmers. Traditional rice farmers in hilly areas, where input of agro-chemicals are low, could be encouraged to grow organic rice. The potential for such rices also is quite high in Bangladesh. Rices with curative value for various ailments have potential for value addition and scope in modern food industry. Rice collections surveys made in the 1970s and 1980s in the Chattisgarh belt of Madhya Pradesh in India have led to the identification of several rice varieties of medicinal value (Siddiq 2002). Collection, inventorisation, and conservation of such valuable germplasm deserve due attention from the National Bureau of Plant Genetic Resources. The scope of such rices for export remains to be tapped.

Rice Research and Development: Impact on Production

The development of the modern semi-dwarf rice varieties and the use of increased inputs of fertilizer, irrigation, and crop protectants ushered in the first phase of the Green Revolution in rice growing countries (Fischer and Cordova 1998, Swaminathan 1999). Loans made available for development of irrigation infrastructure and conducive government policies led to widespread adoption of the new technology. The impact on food supply was immediate. This followed the development of seed multiplication infrastructure and seed distribution by extension systems, training of rice scientists and extension personnel in the way of the new generation of rice production technologies. With this also began the collection and conservation of rice genetic resources and their evaluation and utilization in rice breeding programmes.

The second phase of green revolution emphasised on stabilising yields by incorporating resistance to multiple pests and diseases and also reducing the growing period of rice cultivars. Other developments included introduction of farming systems methodology and mechanization of land preparation and threshing. The international sharing and testing of rice germplasm was also initiated and formalized.

These concerted efforts led to increased productivity, self-sufficiency, and even surpluses in many countries of South and Southeast Asia. In Asia as a whole, rough rice production shot up from 240 M tonnes in 1956 to 513 M tonnes in 1996, an increase of over 114 per cent over 30 years. This increase in production, which surpassed a population increase of 82 per cent in Asia during the same period, resulted in increased per capita availability of rice. The average rice yields in Asia increased from 2.1 t/ha in 1966 to 3.8 t/ha in 1996, an increase of ca. 2 per cent per year. The green revolution in rice was most dramatic and most successful in irrigated rice ecosystem. But large parts of South and Southeast Asia, where rainfed lowlands are the predominant rice ecosystems, have less benefited from rice revolution. Consequently, the yield growth has remained slow, at 1.4 per cent per year, much below the population growth rate.

More than three decades have passed since the advent of green revolution, and there are some concerns that the potential of the green revolution technology might have already been exhausted. A new green revolution is required so that at the prevailing price levels, the increased demand for rice by 50 per cent to 60 per cent over the next 30 years could be achieved. Accordingly, the new research targets focus on increasing yield per hectare by capturing the yield potential of existing cultivars and pushing the yield frontier up with tropical hybrids and new plant type, enhancing input use efficiency by increasing nutrient and water use efficiency, reducing labour costs, implementing integrated pest management, and sustaining resource base in the irrigated ecosystem.

Modern tools and procedures of genomics, cell culture, molecular biology, genetic engineering which, compared with traditional breeding methods, are more precise and rapid with high turnover are being deployed for new breakthroughs in yield potential. Significant strides have been made in hybrid rice research and hybrid rice farming has become a ground reality in India. The hybrid rice technology confers a 15 per cent yield advantage over the best inbred varieties. The technology is also spreading in Bangladesh. Efforts are underway to enhance the heteroic level of the tropical hybrids to make hybrid rice cultivation more profitable. Possible development of apomictic hybrids, which would avoid the need for F_1 seed production, would make the technology even handy for the poor resource farmers. Similarly, the prototypes of the new plant type are already at the field-testing stage and are likely to reach farmers' fields soon. These genotypes promise about 20 to 25 per cent increase in yields (Khush 199[illegible]). Linking heterosis to still more desirable traits, such as insect and disease resistance or tolerance to abiotic stresses, such as salinity and alkalinity, can help the crop perform even better and substantially offset the cost of production.

For impact on rainfed rice, the research targets are focusing on developing tolerance to abiotic stresses, maintaining natural resilience of ecosystem to pests, supporting direct seeding methods for crop establishment, incorporating micro-nutrients in rice, and improving grain quality. If the rice research could succeed in incorporating traits that help modern varieties withstand abiotic stresses and maintain high yield, then such varieties will be adopted readily and more extensively in the unfavorable ecosystem because the risk in cultivation will be reduced. Farmers will have the incentive to apply chemical fertilizers at optimum levels, which will further improve rice yields.

Modern biotechnology tools can enhance these efforts by increasing the efficiency of conventional breeding and by using genetic engineering to bring non-rice or alien genes into the rice gene pool (Bennett 1995), enabling selection of genetically complex traits with high precision and monitoring of changing virulence in pests. Some of the promising research programmes in progress are engineering resistance to stem borer, leaffolder, bacterial leaf blight, sheath blight, and rice tungro virus, and improving nutritive quality by increasing ß-carotene (vitamin A) and protein content using novel genes from near and distantly related life forms. However, the commercial application of biotechnology products in general may still be somewhat problematic. A major policy issue is the regulatory climate governing the release of genetically engineered products or generically modified crops to ensure public health and environmental integrity. The countries in South Asia, including India, have yet to equip with necessary regulatory mechanisms to import, test, and use such materials. Intellectual property protection and plant breeder's right may further delay easy access to materials developed through the use of biotechnology tools.

Although concerted efforts to improve rice production in rainfed ecosystems began only about a decade ago, the progress is quite encouraging. Two major developments that took place in early 1990s, greatly spurred research of rainfed ecosystems. IRRI organized the research programme according to the rice ecosystems that ensured adequate support and opportunities for rainfed rice. The rice research consortia that also began operating early 90s, brought together the resources from NARS in South Asia and IRRI to solve the problems of individual rice ecosystem in a concerted and systematic way by sharing resources and responsibilities. Table 7 gives participatory sharing of responsibilities for conducting strategic research under the Rainfed Lowland Research Consortium. The results are already there to show the impact of these complementary efforts. With lager and better trained scientific staff, deeper and broader knowledge of rice production problems and constraints, increased emphasis on applied as well as strategic research issues, and greater motivation of scientists, the Asian NARS are contributing substantially to the development of technologies that will increase and sustain higher production of rice in their own countries and in other rice growing countries of the world.

Some Emerging Concerns

By 2025, 50 per cent to 60 per cent more rice needs to be produced. However, the land, labour, and water, the basic resources responsible for production are getting increasingly scarce and fatigued and are in need of efficiency gain. Pollution of soil, water, air, bio-mass, and

Table 7. Key sites and their research focus of the Rainfed Lowland Rice Research Consortium in South Asia

Country	Key site	Institute/ region	Research focus/ expertise
Bangladesh	Rajshahi	Bangladesh Rice Research Institute (regional station)	Moderate drought, photoperiod sensitivity
India	Cuttack, Orissa	Central Rice Research Institute	Agricultural Engineering and socioeconomics
	Polba, Chinsurah West Bengal	Expt. Station, Polba and Rice Research Station, Chinsurah	Stagnant flooding
	Faizabad, Masodha	Expt Station, N. D. Agricuiltural University	Salinity/shallow flash flooding
Indonesia	Jakenan, Central Java	Jakenan Expt. Station (under Sukamandi Research Institute for Food Crops)	Dry direct seeding ('gogo rancah'), potassium deficiency
Philippines	Batac, Ilocos Norte	Philippines Rice Research Institute	Long-term sustainability of production systems
	Tarlac, Pangasinan		Rainwater conservation, nutrient, tillage properties
Sri Lanka	Bombuwela	Regional Agric. Research Centre	Iron toxicity, brown spot
Thailand	Ubon	Rice Research Centre, Ubon	Severe drought/ poor soil physical problems, low soil fertility, and phosphorus deficiency, rice blast, weeds

production of greenhouse gases is also being linked to inefficient use of agro-chemicals and agri-inputs. There is thus an urgent need for a thorough assessment of the opportunities for increasing land productivity, including crop diversification. Similarly, as the opportunity cost of family labour rises, given alternative employment opportunities, there is need for labour-saving technologies. Growing water scarcity for irrigated rice ecosystem is another serious challenge for which, while technological options, such as recycling, exist, but little has been done in respect of complementary policies. At present, more than 5 tonnes of water is needed to produce a kilogram of rice.

The irrigated rice environments not only face increased competition for water, but also face reduced water supplies due to system degradation and reduced investments in infrastructure development. In South Asia, the growth rate in irrigated area has dropped from 2.8 per cent during 1975-80 to 0.1 per cent during 1985-88 period (Rosegrant and Swendsen 1992). It is absolutely necessary that technologies that are promoted must sustain rather than degrade the long-term productivity of the resource base.

Since the beginning of 1990s, unit production costs are beginning to rise and rice farmers are facing declining profits. The stagnant yield frontiers and diminishing returns to further intensification are the primary reasons for the current reversal in rice profitability. Further, rapid withdrawal of labour, division of land to other uses, increased competition for water, and withdrawal of subsidies on agricultural inputs have all led to increasing the cost of rice production. In the absence of shift in yield frontiers for rice and/or a substantial improvement in input use efficiencies, the profitability of rice production in Asia may revert to the pre-green revolution era.

The South Asian countries made a great leap in food production over the last three decades. The technological innovations complemented by public investments and policies that promoted intensive rice production systems helped bring about the change in food supply. However, there is a growing sense of complacency about the current and future food supplies in this region. Lack of concern is seen in declining national budgetary allocation for maintaining existing rice infrastructure, including irrigation, reduced bilateral and multilateral donor support for expanding irrigation, a deliberate policy shift towards diversification out of rice, and a substantial cutback in research funding at both national and international levels. Emphasis has shifted to natural resource management and environmental sustainability. However, there are signs that this complacency is not warranted, as greater challenges for producing extra rice in future exist.

Although currently the countries of South Asia are pursuing the policies for achieving self-sufficiency in rice production, it is anticipated that over the next two decades, some of them may have to go for rice import to make up for further domestic shortfalls. Pingali *et al.* (1997) have indicated that domestic shortfalls could occur due to: (i) continued and unabated population growth, (ii) rapid economic growth in some countries that will make the maintenance of self-sufficiency unprofitable, and (iii) trade liberalization and agreements that could lead to Asian food sector becoming more open to international competition. While the short-term effects of GATT agreement could be modest, the long-term effects could be substantial (Pingali 1995). Small countries that are self-sufficient now in rice, may find it profitable to import at least a part of their rice requirements in exchange of diverging production resources to more remunerative activities. However, for countries with large rice-eating population and low-income, such as India and Bangladesh, achieving food security through imports may not be possible due to high volume involved and foreign exchange constraints. For these countries, increasing productivity on rice lands should remain a top priority.

Among the technological options, hybrid rice is a commercially viable technology with 15 per cent yield advantage over the best inbred varieties. India, first among the countries outside China to develop and commercialise hybrid rice technology, however, has yet to take full advantage at the desired level. As against one million hectares targeted for 2000, not even one-fifth could so far be planted to hybrid rice (Siddiq 2002). Inability to meet the seed demand, a factor that contributed to slow pace of adoption, would have to be overcome. Also, hybrid seed quality would have to be ensured to avoid inconsistent yield performance.

Free exchange of rice germplasm provided unlimited resources for rice improvement programmes and sharing of improved materials among the rice growing countries. However, due to imposition of the intellectual property rights and other WTO requirements, the restriction on germplasm exchange is fast growing. Under these circumstances, countries with poor genetic resource base and not-so-well developed research set-up, such as Nepal and Bhutan, would face difficulties in accessing improved rice germplasm. The countries in South Asia could, however, develop some collaborative mechanisms to ensure exchange and use of rice germplasm among themselves without affecting each other's interest and sovereignty right. Adequate increase in budgetary support for rice research and development is long overdue in countries in South and Southeast Asia so that it becomes comparable to that in developed countries.

The seed-fertilizer technology of green revolution era was simple and its impact was easily visible. The new technology which deals with complexity of the natural resource management, input use efficiency, and sustainability needs clear understanding and better skills for its transfer and adoption. Its impact also is slow, but with long-term effects. The challenge for the research system is in finding efficient and cost-effective methods for transferring knowledge-intensive crop management technologies to farmers. The ultimate goal is to have farmers who are capable of deriving the appropriate recommendations for each farmer's field using 'if-the' type analysis. The current practice of providing blanket recommedations of fertilizer application to farmers over large areas is no longer a valid mode of operation for extension workers. To reduce knowledge gap, the extension services in future would have to transfer knowledge and provide decision-making options rather than straight input use recommendations. The extension technicians and farmers, therefore would have to be well trained, and the scientists more responsive to convince farmers of the importance of the technologies and how they work. Information technology could play an important role in rice production and natural resource management. It would require upgrading of educational curricula of agricultural schools and colleges. India, being a leader in the field of information technology, could gain substantially by introducing precision farming approaches at farmer level.

The application of modern technologies, such as biotechnology, remote sensing, meteorological information for medium and long-term forecasts, crop modelling, geographic information system, etc., requires trained personnel and state of the art research facilities. Except, perhaps, India, few other countries in South Asia have the required capacity to absorb and utilize these technologies for the benefit of rice production. Working closely with advanced laboratories or through the International Rice Research Institute could therefore be advantageous. It would be detrimental to agricultural economy as a whole, if these countries are left behind in harnessing the benefits of these advanced technologies in solving some of the present problems. Also substantial policy reforms ought to be in place before the fruits of biotechnology would become available to the rice farmers in South Asia.

A holistic food security policy need not be anti-environment; it can actually contribute to long-term environmental sustainability. Rational food production systems that improve the efficacy of inputs and resource use, help conserve the natural resource base rather than threaten it.

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Current Status of Molecular Rice Breeding in Vietnam

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Introduction

Biotechnology is considered as a tool originated from many disciplines including molecular biology, genetics, microbiology, bio-informatics, biochemistry. Biotechnology has been applied in agriculture as a breakthrough measure to aim at developing a sustainable agriculture. The development of DNA-based techniques and their application to plants opened new possibilities for rice. In Vietnam rice is a staple diet and therefore it received considerable attention in improving its productivity and quality. Recently, efforts are underway to use biotechnological means to improve crop production, with rice receiving attention. Considering the costs involved in setting up biotechnology based breeding systems, the country needs to develop a strategy in furthering its adoption.

In Vietnam policy are being devised to enhance the cultivation of rice from 4.3 million ha to 7.6 million ha and production has increased from 15.7 million tons in 1985 and 34.5 m tonnes in 2003. Average rice yield obtains 4.67 t/ha today. The idea is to feed the current population in Vietnam of 81 million people. However, with the onslaught of

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urbanization and other reasons up to 4.0 million ha may be reduced. Beside that, water shortage, salt intrusion will become serious problems and a big challenge for human life. Rice is one of the most important food crop in the country providing 67 per cent calories on an average to an individual in the country. Rice production was increased.

The Vietnamese Government has set up a National Biotechnology Programme through regulation 18/CP (projection from 2000 to 2010) to look into the need of trained manpower and investment for research and development. The budget has been increased year by year (Table 1, and 2), it depends to the economic development of the country. Especially, rice biotechnology projects were supported by the Rockefeller Foundation at initial years, and ARBN (Asian Rice Biotechnology Network), ICGEB (International Center for Genetic Engineering and Biotechnology). Vietnam has to plan both short-term and long-term training systematically to obtain specialists on genomics and others to implement the development. Attentions on rice biotechnology applications have been paid to: (1) gene transformation to improve the traits in which the conventional breeding is not available, (2) double haploid lines through anther culture, (3) DNA recombinant techniques, (4) marker-assisted selection in rice breeding, (5) genetic diversity assessment, did this happen in Vietnam or elsewhere. Again, give references.

Table 1: Budget for national biotechnology programme

Period	Budget (USD / year)
1981-1985	20,000
1986-1990	1,000,000
1991-1995	1,500,000
1996-2000	2,500,000
2001-2002	2,000,000
2003-2004	75,500,000(planned)

Table 2: Funding by national budget for biotechnology project (2003-2004)

	VND $ billion	per cent
Education	150	2.5
Equipment	500	8.2
Agriculture	3,500	57.2
Medicine	1,300	21.5
Industry	250	4.1
Environment	140	2.3

Human resource has been promoted recently: one million USD covers scholarship for training abroad/year in addition of training in the country, including 4 per cent of scholars doing biotechnology. Key national projects on biotechnology (2004-2010) are identified as Project 1: Human Resource; Project 2: Establishment of national key lab; Project 3: Strengthening R&D capacity; Project 4: Biotechnology for sustainable agriculture; Project 5: Biotechnology for public health; Project 6: Biotechnology for industry. There are six national key lab on biotechnology are being set up. However, we have more equipment but less experts now. The scientific manpower must be strengthened and the agenda for biotechnology research must be clear to meet the demand of development.

Rice Monoculture and Low Competitiveness in Rice Markets

Vietnam had obtained one million tonne of paddy increased per year from 1990-2000; however, the income per ha has been a constant (around $US 1010 / ha in 2002). It means that rice-based farming systems are not diverse and not effective. Agro-economic structure conversion is considered to aim at diversify various sources of farmer income and to enrich biodiversity. During last decade, exporting rice became a target of rice production in Vietnam, and the amount of exported rice has been used to access the balance between rice supply and demand. Therefore, it is necessary to evaluate the comparative advantage of rice production in Vietnam. All efforts by rice workers in the country are paid attention: (1) to close yield gap, (2) to sustain current yield, and (3) to break yield ceiling by various ways (including hybrid rice and new plant type). Beside that grain quality improvement is always recommended with the emphasis on intermediate amylose content, long grain, less chalky varieties to sustain current yield, rice improvement has been focused to release new genotypes with stable tolerance to the target stresses and favourable soils for rice culture in two big granaries of the country as alluvial soils are 1.18 m Ha (30.1 per cent) and 0.91 m Ha (48.5 per cent) in Mekong Delta and Red River Delta (Table 3), respectively.

In acid sulfate soils, low pH, aluminum toxicity, iron toxicity, and low phosphorous are considered as main limited factors for rice growing. Currently, water management and agronomic practices have been recommended. Some improved genotypes have been identified to tolerate to drought, salinity, acid sulfate but not stable.

Table 3: Problem soils in rice culture areas in Mekong Delta (MD) and Red River Delta (RRD)

Soil type	Area (million ha)		Percentage (%)	
	MD	RRD	MD	RRD
Acid sulfate	1.60	0.11	40 8	5.95
Salinity	0.74	0.09	18 9	5.23
Peat soils	0.02	0.002	20 0	0.10
Grey soils	0.13	0.15	3 4	8.02

For biotic stresses, brown plant hopper is mainly considered as the most important pest in rice production. Due to the change of population or biotype, in addition to the heavy intensification, current rice genotypes are not stably resistant for a long period. Introgression of target genes from wild rice species into cultivars is being implemented.

Blast disease is also the most important biotic stress. Many isolates were collected in Vietnam, and gene *Pi-2* is considered to control almost virulent races in Vietnam beside other genes. Farmers are misusing fungicides and other chemicals in their rice field to break the natural balance and create new races so that no current cultivars are showing their stable resistance after two seasons

Bacterial leaf blight is the main problem in North at both main seasons, and in South in monsoon season. Genotypes with *xa-5, xa-13, Xa-7, Xa-4, Xa-21* can control the virulent bacteria in Vietnam (Buu and Lang 1998, Buu *et al.* 1999).

Sheath blight is considered as important in both North and South, in any season. No genotype has been identified so far to be tolerant to this disease. Chemical and agronomical practices are used to manage it. Beside that, in Winter-Spring season, there are case worm, stem borer, and in Summer-Autumn, thrips, gallmidge, rice bug. Brown plant hopper break which occurred in 1978-1979, 1985-86, 1992 with million ha in South, is an impressive event in rice production history. Integrated pest management (IPM) has been launched through many campaigns with the respond by farmers, policy makers, and scientists.

Natural calamities such as typhoon, storm, flood are also risks in rice production every year. Three basic climate regimes are found in Vietnam:

- In the North, especially in the interior, the temperature are subtropical, cold tolerance is needed in Spring season, flood type is sudden flood in monsoon, submergence tolerance is required.

Shifting seasonal wind patterns result in dry winters and wet summers.

- The Central and Southeastern areas are in tropical monsoon climate, with high temperature and abundant precipitation, with the emphasis on typhoon in coastal Central.

In the Southwest, distinct wet and dry periods are evident, but stagnant flood is typical from August to November. Post-harvest losses of rice in Vietnam range from 13 to 16 per cent as compared to 10-37 per cent in Southeast Asian countries, mainly due to harvesting, drying, storage and milling. Post-harvest losses vary by seasons and regions with 15 per cent in South Coastal Central, 13 per cent in Mekong Delta, and 10 per cent in Red River Delta.

Research and Its Impact

Ministry of Agriculture and Rural Development (MARD) has many research institutes and centres undertaking responsibility of food research including CLRRI. Programme "KN01-Food Crop Research" had 19 projects of which 18 are implemented by MARD, and "KC18-Biotechnology" with 18 projects of which 4 are implemented by MARD

Total researchers for food crops in whole country is 819 while the researchers with PhD degree 145 (17.7 per cent) and the researchers with MSc. Degree 124 (15.0 per cent) while the post-graduated researchers account for 32.7 per cent in terms of food crops. Varietal improvement has provided farmers with the best materials avialable from pure line selection, introductions, and local hybridization. About 5,000 accessions of local rices and hundred populations of four wild rice species: *Oryza rufipogon, O. nivara, O. officinalis, O. granulata* have been collected, catalogued and evaluated. This resource material has provided donors for biotic and abiotic stresses (Buu *et al.* 1997). Rice germplasm evaluation assited by DNA markers has been conducted at some institutions in Vietnam, to supply a reliable information to rice breeders while selecting appropriate materials. The extra early rice varieties with 80-90 days duration, and early genotypes (91-105 days) created a new strategy to escape flood by growing them before and after flooding to increase more rice seasons in the Mekong Delta. Growing rice areas have increased from 2.2 million ha in previous 1990's to 3.9 million ha/1.7 million ha of cultivated areas up to now due to improving short duration genotypes. The shortcoming has maintained for many years that they never mind the quality of their seeds so that seed technology should be mentioned in further development strategy.

Vietnam has become a rice exporter, and grain quality improvement has just set up as top priority in rice improvement program. Intermediate amylose, intermediate gelatinization temperature, no chalkiness, long slender grain are the criteria of breeding objectives in terms of grain quality improvement. We successfully released some high yielding varieties (HYVs) with long grain shape and translucence. All efforts have been done to improve intermediate amylose content. The effect of waxy and non-waxy gene dosage, and endosperm appearance is continued to study. Seven new varieties released in 2002 with the emphasis on grain quality and high yield as DT122, NX30, CH5, P1, MT58-1 in Red River Delta and Northern parts AS996, OMCS2000 in Mekong Delta and Southern parts.

Some genotypes tolerant to biotic stresses like brown plant hopper, blast were commonly used. The exploitation of gene pool from wild rice species fruitfully obtained a true introgression of desirable traits into HYVs such as AS996 (IR64/*Oryza rufipogon*) which is tolerant to some major biotic and abiotic stresses, short duration, yiel yield, wide adaptibility. The inbred rices from CLRRI now occupy more than 60 per cent of cultivated rice areas in the Delta. Hybrid rice has been quickly developed in Red River Delta with 480,000 ha in 2001, and 530,000 ha in 2003. Beside three-line system varieties introduced from China such as San You, Vietnam Hybrid Rice Research Centre has tried to develop HYT83, HYT84 in Spring, 25A / PM3 in monsoon season. Two-line system with gene *tgms-2, tgms-2, tgms-3* is also exploited to develop promising varieties.

Available Applications on Rice Biotechnology

1. Biodiversity

Germplasm conservation is the first step for application of biotechnology. Because genetic erosion becomes serious everywhere in the world including Vietnam. By the DNA recombinant technology, genetic diversity is possibly assessed Domestic and exotic germplasms have been collected and preserved including landraces and wild species They need to be characterized and evaluated both phenotyping and genotyping with a cumbersome work. Due to the current applications on biotechnology such as detection of candidate genes, gene profile, allele mining techniques, they can enhance the process of germplasm conservation for evaluation and utilization. Database management will be facilitated by bio-informatics development. Genetic variation will be also enhanced through double haploid (DH) populations, advanced backcross (AC), recombinant inbred lines (RIL), nearly isogenic lines (NIL), introgressive lines from wide hybridization. Map-based cloning is encouraged as a key strategy in genome analysis.

2. Cloning

Development of vectors such as plasmid, cosmid, BAC (bacterium artificial chromosome) has facilitated to clone target genes, to approach genome libraries, or cDNA libraries, to form gene constructs for transformation.

BAC clone library has been set up to identify target genes as *Xa-21, Bph-10* cDNA libraries for target traits which control tolerance to major biotic and abiotic stresses have been carried out.

3. Marker-assisted selection (MAS)

Marker-assisted selection has been considered as a good strategy since 1995 for crop improvement in developing countries. PCR-based markers such as RAPD, AFLP, STS, microsatellite can be used to detect target genes in parent and progenies lines. "Fine mapping" is the key of the strategy through a careful selection of parental materials with typical genotype of susceptible and resistant one to a target objective.

Cuu Long Delta Rice Reseach Institute (CLRRI), Agricultural Genetics Research Institute (AGI) have focussed MAS to fruitfully investigate resistant rice genotypes to brown plant hopper, blast, and bacterial leaf blight.

4. Introgression of target genes from wild rices

Target genes from wild species related to a given crop can be introgressed into cultivars through embryo rescue technique in term of two different genomes. Chromosome manipulation can be facilitated by FISH (fluorescent *in-situ* hybridization) in terms of wide rice hybridization. One variety was released through crossing between IR64 x *Oryza rufipogon* collected in Dong Thap Muoi (strongly acid sulfate soil). It has been well developed in less-favorable areas in the Mekong Delta.

5. QTL analysis and QTL mapping

Most of economic traits are controlled by polygenes, and some complex genes e.g. blast resistance are controlled by both major and minor genes. They require quantitative trait loci (QTL) mapping such as drought, salt tolerance, P deficiency tolerance, aluminum toxicity tolerance, etc. GxE interaction is a challenge for QTL analysis, it needs a well-modified software to interpretation of outputs.

PCR-based markers can be simply used but they have to cover all chromosomes with closer linkage between genes and markers.

6. Cellular techniques and gene transformation

Anther culture can be applied to exploit homozygosity quickly and micro propagation is also considered as a progressive technique in developing countries.

The development of DNA-based techniques, generally known as biotechnology, and their application to plants opened new possibilities for seed businesses. Genetically modified crops (GMC) have received some great achievements recently, but they have also received a lot of criticisms.

Two different viewpoints in well-developed countries on GMO. They are often conflict viewpoints. Instead of in developing countries, their common attitudes are hesitation and waiting because they do not own any GM crop serving to export purpose and they do not need to import GM crops.

GMO should be scientifically investigated and need more time to conclude. Risk assessment is requested.

For rice transformation, normally immature embryos or calli were used as explants for transformation. Embryogenic suspension cells of indica rice cutivars were successfully used in the *Agrobacterium*-mediated transformation.

Selectable marker has been improved such as *pmi* with mannose selection procedure.

7. Functional Genomics

Since 1999, special term has been created as "functional genomics" to mention a new aspect on genomics in order to detect more candidate genes with their special functions with two major tools: (1) whole genome expression analysis, (2) systemic gene disruption, with the goals as followed:

- to create an information mode to deposit and disseminate information in crop functional genomics,
- to build a public platform to promote access to genetic stocks and phenotypic information,
- to develop databases on phenotypes and mutants with linkage to sequencing laboratories, and
- to initiate partnerships to develop resources for microarray analysis

Attentions on gene discovery should be paid through the collaboration which belongs to the international rice functional genomics consortium (IRRI).

Concluding Remarks

Rice production in Vietnam has successfully increased due to research collaboration with IRRI and others. Vietnam is trying its efforts for setting a sustainable agriculture. All rice research activities aim at diversifying natural resources, maintaining natural balance in rice field. It is so called "integrated management".

Attentions on the biotechnology applications in rice have been paid to: (1) gene transformation to improve the traits in which the conventional breeding is not available, (2) double haploid lines through anther culture, (3) DNA recombinant techniques, (4) marker-assisted selection in rice breeding, (5) genetic diversity assessment. Rice biotechnology has significant potential to help agriculture contribute to the goal of sustainable development:

- to increase the production and productivity of crops
- to increase the nutritional and market values of food
- to enhance the stability and sustainability of agro-ecosystem
- to mitigate the deleterious impacts of agro-ecosystems

Priorities will be considered as (1) marker-assisted selection and (2) using the advantages of gene transformation with clean DNA construction. Vietnam needs to increase capacity building biotechnology to rice improvement and to receive assistance in preparing bio-safety regulations. The integration of biotechnology tools with conventional breeding methods offers new opportunities to increase rice productivity and sustainability, achieve food security and improve nutritional quality. Existing biodiversity of rice varieties and their nutritional composition need to be explored before engaging in transgenic. The potential of the genetic diversity has not been adequately utilized. We need the collaboration to make better use of this potential latest biotechnological methods employed in conjunction with conventional rice breeding program.

Attentions will be paid to enhance rice grain quality to meet the demand of common international preferences on long grain appearance with/or without aroma. Varietal improvement and post-harvest technology should be included. Vietnam needs the collaboration on revising policies with the least distorting effects on the world rice market

IRRI has been working with hybrid rice since 1979. Work continues on increasing cytoplasmic diversity in CMS three-line hybrids. The new two-line system has shown stable pollen sterility. Vietnam is focusing research efforts to develop hybrid varieties with acceptable grain quality and bacterial leaf blight resistance.

Narrowing yield gap is considered as a key strategy contributing significantly to increase rice production in the country. The adoption of rice integrated crop management (RICM) has demonstrated great potential to facilitate the adoption of improved management practice and technology by farmers to improve yield, grain quality, reducing production cost and protect the environment, e.g. current "Three Reduces Project" by IRRI in Mekong Delta (reducing seed rate, N fertilizer, pesticide). Vietnam needs to promote RICM through extension farmer schools following the effective approach, such as *Ricecheck* methods, to narrow the yield gap and enhance food security, to converse some rice farms into more advantageous farming system (i.e. shrimp) but ensuring food security goal. Vietnam needs to formulate policies to encourage incentives and support for the development and transfer of RICM

Resources and policies should be adequate to promote appropriate rice drying, rice storing in small metallic silos, rice cleaning how to increase the quality of commercial rice in the market.

Collaboration Delivery Opportunities

Enhancing the value of international rice gene bank collection by discovering novel alleles for the development of nutritious rice adapted to fragile environments: these approaches will include high-throughput DNA microarray technologies, highthroughput genotyping (HTG) methods which will allow mass screening of gene bank accessions for alleles at many candidate gene loci.

There is also a need to enhance water and land productivity through alternating wetting-drying irrigation and root zone aeration in irrigated rice and development of technologies to harness the productivity potential of salt-affected areas: to (1) introduce salt tolerance genotypes adapted to main salt-affected areas and to different farming systems, and (2) develop integrated crop management suitable to the demands of natural resource management packages. Some perspectives for the dissemination and marketability of environmentally sound rice production technology in the Mekong Delta may be further developed. Vietnam is emerging as a key partner in the global rice research community. Vietnam-IRRI collaboration and other countries from the Mekong River and Asia will address the farming community in its entirety so that Vietnam can be assured of rice security, the income of farming families will increase, and the environment will be protected.

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Biotechnological Options for Enhancing Water Use Efficiency of Rice

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Rice is the staple food in Asia, the most populous continent, which accounts for almost 90 per cent of the global production and consumption. This demand is likely to increase by 70 per cent in the next three decades for the ever-increasing Asian population (Hossain, 1997). Asia produces more than 530 million tonnes of paddy rice every year. More than 75 per cent of this comes from the irrigated area, which accounts for 55 per cent of the total rice area (Bouman, 2001). Irrigated low land rice constitutes the major economic activity, source of employment and income for the rural population. In India out of the 43 million hectares under rice cultivation, almost 50 per cent is irrigated which consumes almost 50 per cent of the irrigation water resources. The growing water shortage has threatened the sustainability of irrigated low land rice production systems, which consumes up to 5000 liters of water to produce 1 kg of grain (Bhuiyan, 1992). Fresh water consumption for irrigated low land transplanted rice in most Asian countries is, therefore, very high. Fresh water is a scarce resource and getting scarcer every passing day (Tuong and Bouman, 2003).

Since rice is the staple food of billions, it is imperative to devise technologies of growing rice with less water, reducing dependence on

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traditional methods of growing rice, without any compromise on production. Breeding rice varieties for enhanced water use efficiency and drought tolerance using the modern tools such as Marker Assisted Selection (MAS) breeding and genetic engineering is necessary to enhance and sustain the rice production at a higher level. It is now the need of the hour. Water use efficiency (WUE) is generally defined as the amount of dry matter (or grain yield) produced per unit of water consumed. It can also be defined as the ratio of photosynthetic carbon assimilation to transpirational water loss. Total biomass produced is, therefore, equal to total water use X WUE. The total water use and WUE of crop plants can be improved by 1) maximization of water uptake from the soil to support maximal photosynthetic rates, 2) minimizing water loss through plant architecture such as modified stomata and cuticle stomatal and cuticle) without reducing photosynthesis, 3) enhancing the production per unit quantity of water used, and 4) cellular tolerance to water deficit.

Maximization of Water Uptake from the Soil

The roots play pivotal role in water and nutrient uptake, and act as sensors of water and nutrient status of the soil. Under rainfed unirrigated/inadequately irrigated conditions, possession of a deep and thick root system and other root morphological traits that allow access to water and nutrients from deeper soil layers will be one of the most promising of traits for improving WUE. In addition to it, the ability of plants to cool their canopy temperature through transpiration needs efficient functioning of the root water uptake system. The actual measurement of root morphological and other traits, that contribute to enhanced water uptake under field drought conditions, require a whole crop season in addition to other resources. Hence efforts were made to identify the quantitative trait loci (QTL, genomic locations of genes controlling a quantitative trait) for root traits and tag it with molecular markers. Once QTLs are tagged with molecular markers, these markers can be used to screen and select the desired plant type (with desired QTLs) from the segregating population even in the seedling stage in the lab conditions. Thus MAS of genotypes help in increasing the accuracy of breeding and at the same time reduces the time and other resources requirement. QTLs controlling root morphological traits in rice (Babu *et al.* 2003; Courtois *et al.* 2003; Zheng *et al.* 2003) have been identified by using molecular markers. Currently efforts are being made to introgress QTLs for root traits in MAS breeding for enhanced drought tolerance and WUE (Steele *et al.* 2002).

Minimization of Water Loss

Water loss from the plant to the atmosphere occurs through transpiration mediated by stomata and direct evaporation of water from epidermal cell surface. Of these two, water loss through stomata occounts for majority of the water losse. Stomatal pores allow CO_2 influx for photosynthetic carbon fixation and water loss via transpiration to the atmosphere. Thus, the rate of transpiration and photosynthesis depends upon the plants ability to regulate its stomatal pores. The stress hormone, Abscisic acid (ABA) synthesized by root under receding soil water conditions or by leaf when the transpiration exceeds water uptake act as signal to control stomatal responses. Genetic analyses of stomatal regulation in *Arabidopsis* have led to the identification of genes that control stomatal response to water deficit (Schroeder *et al.* 2001). QTLs for traits that minimize water loss through plants such as controlling stomatal regulation (Price *et al.* 1997), leaf ABA accumulation (Quarrie *et al.* 1997) and leaf rolling (Courtois *et al.* 2000) have been identified and tagged with molecular markers in rice. These QTLs and genes involved in minimization of water loss can be used to genetically modify the stomatal regulation and improve WUE.

Enhancing the Production per Unit Quantity of Water Used

The WUE of plants can be enhanced by genetic modification of plants for higher harvest index, spikelet fertility, stay green traits, seedling vigour, and short duration and reduced photorespiration. Now QTLs have been identified for some of these traits in rice and efforts are being made to identify the genes and understand the molecular basis. Molecular markers that are linked to QTLs that control panicle sterility and reproductive traits (Lanceras *et al.* 2004) have been identified in rice. Since WUE is a complex trait and determination of WUE under field condition needs accurate measurement of water and carbon budget of plants. During photosynthesis, plants with high water use efficiency show less discrimination to $^{13}CO_2$ to $^{12}CO_2$. Hence, ^{13}C-isotope discrimination by photosynthesis has been successfully established as surrogate for WUE. Breeding for $^{13}CO_2$ discrimination trait in wheat lead to the release of wheat variety with enhanced drought tolerance (http://www.csiro.au/proprietary Documents/PI_info_Rees.pdf). High water use efficiency has been found to be associated with low ^{13}C-isotope discrimination in rice (Peng *et al.* 1998). Identification and molecular marker tagging of QTLs controlling $^{13}CO_2$ discrimination and application of this approach in rice will therefore help in enhancing WUE.

Cellular Tolerance to Water Deficit

Cellular water deficit stress tolerance in plants depends upon the expression of genes involved in production of organic compatible solutes (proline, sugars, polyols, betaine, etc.), late embryogenesis abundant (LEA) proteins and antioxidants. They protect plants from stress by (1) osmotic adjustment which helps in turgor maintenance, (2) detoxification of radical oxygen species, (3) stabilization of the quaternary structure of proteins, and 4) allowing the plant to extract water at low soil water potential. Transgenic rice plants engineered to over-produce organic compatible solutes such as glycine betaine (Sakamoto *et al.* 1998), proline (Su and Wu, 2004) and trehalose (Garg *et al.* 2002) showed enhanced tolerance abiotic stresses including drought. In addition to that, QTLs that confer osmotic adjustment have been identified in rice using molecular markers (Zhang *et al.* 2001).

Transcriptome engineering or overexpression of a master switch gene (such as stress sensors, protein kinases or transcription factors) that regulate several target genes coding for osmolyte biosynthesis enzymes and LEA proteins is emerging as an important tool to combat abiotic stresses. Transgenic overexpression of a stress inducible calcium dependent protein kinase (OsCDPK7) in rice increased cold salinity and drought tolerance (Saijo *et al.* 2000). The *Arabidopsis* DREB1A transcription factor controls the expression of several *LEA* genes and genes code for osmolyte biosynthesis enzyme. Wheat transgenic plants overexpressing *DREB1A* gene showed lower canopy temperature (1-2°C less), relatively higher water content and enhanced drought tolerance under field condition (Pellegrineschi *et al.* 2004). Transgenic rice plants overexpresing of *DREB1A* gene has been shown to impart abiotic stress tolerance under lab conditions (Oh *et al.* 2003). IRRI is currently developing transgenic rice plants with *RD29A* promoter driven *DREB1A* gene from *Arabidopsis* (Datta, 2002).

MAS appears to be successful in producing promising plant type for enhanced WUE and drought tolerance (Steele *et al.* 2002). However, QTLs can vary from population to population and are influenced by the growing environment. Therefore identification of QTLs under near realistic field stress conditions will enhance pace of its use in molecular breeding and genetic engineering. Map based cloning of major genes that control the QTLs involved in WUE and drought tolerance and validating their function in rice transgenic will be an important step towards genetic engineering and molecular breeding to enhance WUE in Rice. Since the preliminary field test results of *DREB1A* transgenic wheat at CIMMYT (Pellegrineschi *et al.* 2004) and result from *DREB1A* transgenic plants of rice (Oh *et al.* 2003) showed that transcriptome engineering can enhance the drought tolerance, transcriptome engineering appears to be a promising method to engineer drought tolerance in rice.

Non-biotechnological Options for Improving WUE

As stated earlier, water is currently the most limiting input for crop production and the most vital resource for all developmental related activities in general, and agriculture, in particular. Undoubtedly, judicious management of water is critical for the sustainability and dependability of rice production. Developing rice varieties that have higher water productivity is one aspect of the strategy but it can be targeted to only one component of the field water balance, i.e. transpiration. At the field level, there are several other processes that contribute to non-productive water losses. Therefore reduction in water losses due to other components of the field water balance will result in an increase in WUE and can contribute significantly to overall water productivity of a system. Laser leveling, mulching and following an optimum irrigation regime are options that can enhance water productivity significantly. Contrary to the earlier belief, rice does not

Table 1. Management Options and Strategies for Improving Water use efficiency in Rice

Management options	T	E	SP	SRO	RCL
Developing improved varieties	x				
Improving agronomic management	x				
Changing schedules to reduce evaporation		x			
Reducing water for land preparation		x	x	x	
Changing rice planting practices		x	x	x	
Reducing crop growth water		x	x	x	
Making more effective use of rainfall			x	x	
Water distribution strategies		x	x	x	
Water recycling and conjunctive use					x

require standing water and it has been tested and proved beyond doubt that intermittent irrigation or irrigating the rice crop one to two days after disappearance of ponded water from the soil surface will not affect the yield significantly. This practice alone can save 20 to 30 per cent of irrigation water. Table 1 summarizes the various options available for enhancing water use efficiency in rice. In the Table 1, "T" is the transpiration and "E" is the evaporation component of crop evapo-transpiration, "SP" represents seepage and percolation losses, and "SRO" is the surface run off. It is possible to re-use some fraction of the seepage and percolation losses as well as surface runoff, i.e. they can be recycled within the system and are symbolized by "RCL" (Guerra *et al.* 1998).

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Bio News

This section puts together news about the recent and key developments related to Rice in the Asian region.

IRRI and CIMMYT to work jointly for 'Asian Crops'

The International Rice Research Institute (IRRI) and the International Maize and Wheat Improvement Center (CIMMYT) have formed an Alliance to coordinate research efforts on rice, wheat, and maize aimed at improving the lives of poor farmers. The Boards of Trustees (BOT) of the two international centers who met in Shanghai, China recently identified four research priorities for potential first programmes of the new Alliance:

- Intensive crop production systems in Asia – specifically, rice-wheat and rice-maize – and research on crop and resource management, crop genetic improvement, and socio-economics. Cereals information units to provide information for researchers and partners working on genetic improvement and the management of cropping systems involving the three staples.
- Training and knowledge banks for the three crops that would take advantage of modern technologies to provide training events, the development of learning materials and education methods, distance learning, Web-based knowledge systems, library services, and logistical support.
- Climate change research directed at both mitigating and adapting the three crops to global changes that are affecting temperature, water, and other factors having crucial effects on them.

The IRRI-CIMMYT Alliance will also share a range of support services like management and regulatory affairs for intellectual property rights and biosafety, information and communication technologies, public awareness, scientific publishing, library services, and external auditing.

Philippines targets to be a top rice producer, goes for GM Rice Field-testing

The Philippines will start a multi-location field test of a genetically modified rice variety that is resistant to bacterial-leaf-blight disease. They will try to commence the testing during the wet season when the disease is prevalent. They will do it in plots first. The Philippine wet season falls in the months of May through September. BLB disease is prevalent during the rainy season and affects flood-prone rice areas in the country. Though results of the field test will be reviewed in the initial testing done on the variety has shown it is resistant to the BLB disease.

The Philippine government's massive propagation of the hybrid rice known as "Gloria rice" has spawned a rice revolution in the countryside and caught the interest of major rice importing countries, especially after the United Nations General Assembly (UNGA) declared the year 2004 as the International Year of Rice. Japan, Malaysia and Indonesia are among the countries which have expressed their interest in importing the hybrid rice and seeds being produced in the Philippines.

The Philippines has been noted by the FAO as one of the countries bent on solving its poverty and hunger problems. The Philippines increased its palay (unmilled rice) production by 13.27 million metric tonnes in 2002 resulting in a 93 percent self-sufficiency level and is expected to be fully self-reliant in the next two years because of the massive planting of the hybrid rice by local farmers.

China considers GM rice approval

The Biosafety Committee of the Chinese Ministry of Agriculture is considering the approval of at least four varieties of genetically modified (GM) rice and is expected to make a decision on the approval of their commercialization. If approved, it will be the first time that GM rice is approved anywhere in the world and also the first time Chinese have approved a GM crop for human consumption. Even if approved, however, the Chinese government has indicated that it would conduct additional field trials and tests about the safety of the crops for at least two years, setting 2006 as the expected date when the crop would be available for planting and harvest. Hopes have been riding high on the potential for GM rice to solve the challenge of feeding China's booming population, with one Chinese study suggest that adopting GM rice could result in an annual increased profit to China's agricultural sector of "roughly $5 billion in 2010". China is a centre of origin of rice. The biggest danger is the contamination of wild and conventional rice varieties with GM rice, which can encourage more troublesome weeds and will lead to the loss of wild species. There is a criticism of the approval process that the ministry's "behind closed doors process" was "scientifically and ethically flawed". It is warned that scientists "still know too little about the unintended impacts of genetic modification."

However, China's rice woes demonstrate that ongoing food security cannot be taken for granted - even in one of the world's most dynamic economies. Harvest shortfalls induced by global warming would likely be much more widespread and persistent. Left unchecked, they could undermine global food security and political stability. The poor suffer first and foremost when a succession of meager harvests causes rice shortages and price hikes like those now making headlines in China. The shortfall in the world's largest rice producer and consumer has many apparent causes, and government-orchestrated restoration of planted area will likely revive the Chinese rice sector before it upsets the calm and predictability with which the international rice trade has been blessed for the past couple of decades.

California Rice Commission Approves biopharm rice

The California Rice Commission has approved planting guidelines proposed by Sacramento-based Ventria Biosciences to begin commercial production of plant-made pharmaceuticals derived from a bioengineered rice variety. The Rice Commission is charged with approving protocols of all new varieties of rice in the state that may have commercial impact. Ventria's biopharm rice has been genetically engineered to produce two pharmaceutical proteins, *lactoferrin* and *lysozyme*, commonly used as antimicrobials and antidiarrheals.

However, some farmers have expressed their concerns that Ventria's biopharm rice would contaminate the crops of other rice farmers and ultimately the food supply. They feel that though the approved guidelines restrict production to regions that do not currently grow rice (e.g. Los Angles, Orange, San Diego and seven other Southern California cities) they do not limit how far away the rice is transported for milling, or the location of research fields. These farmers have also charged Ventria for not adequately testing either the human health or environmental effects of their pharmaceutical rice and that the firm has also failed to publicly disclose how they plan to market the rice.

Rice Productivity affected by climate change

Field studies conducted at the International Rice Research Institute (IRRI) have confirmed predictions from theoretical studies that global warming will make rice crops less productive. Combining a quarter century of climate data collected at IRRI with yield trends in adjacent fields over the past dozen years, researchers further discovered that simulation models underestimated the problem by half because they overlooked the pernicious effect of high minimum nighttime temperatures. The results of this study highlight the need for greater fundamental understanding of the effects of night temperature on physiological processes governing crop growth and yield development. The challenges now is to get the financial resources needed to develop new rice varieties that can still yield well despite any increase in temperatures in rice growing areas.

The proceedings of the National Academy of Sciences of the United States of America, found that rice yields at IRRI declined by 10 per cent for every 1ºC increase in seasonal mean minimum temperature. Temperatures are projected to rise globally by 1.5-4.5ºC in the coming century - or 3 to 9 times more than in the past century. Global warming thus threatens to erase the hard-won productivity gains that have kept the rice harvest in step with population growth. Since the dawn of the Green Revolution - which began in Asia with IRRI's release in 1966 of IR8, the first modern, high-yielding semi-dwarf rice variety - the global rice harvest has more than doubled, racing slightly ahead of population growth. This achievement not only averted the mass famine that four decades ago appeared poised to engulf much of Asia, it has also made rice more affordable and so helped unshackle many Asian communities from the treadmill of subsistence agriculture.

The study recorded that the mean minimum nighttime temperature during dry season at IRRI has risen since 1979 by 1.13ºC, or 3 times the 0.35ºC rise in mean maximum daytime temperature. This difference is an expected consequence of increased greenhouse gas concentrations in the atmosphere, and IRRI's climate records are consistent with warming trends found elsewhere in the Philippines and globally. The news is that high nighttime minimum temperatures clearly and strongly suppressed rice yields in the seasons in which they occurred, while high daytime temperatures had no measurable effect. Yields fell by 10 per cent for every 1ºC increase in mean nighttime minimum temperature. Because the increase in night temperature was 3-fold greater than the increase in daytime temperature, rice yields declined by 15 per cent for every 1ºC increase in daily mean temperature - double the 7 per cent decline that emerged from theoretical models. Most studies of temperature and global warming effects on crop growth and grain yield are based on daily mean air temperature, which assumes no difference in the influence of day versus night temperature. This direct evidence of decreased rice yields from increased night temperature associated with global warming. The scientists attributed more than 70 per cent of the year-to-year variation in rice grain yield to nighttime temperature but could do little more than speculate on the mechanism involved.

Concerns expressed as GMO rice trials on in Asia

As Asian countries face growing shortages of essential agricultural resources such as water, land and the labour, the region's rice industry will ultimately be adversely affected. The problems facing Asia is further compounded because rice yields would have to increase at an annual 1 per cent rate over the next 30 years just to keep up with population growth. The people living in Asia makes up 60 per cent of the world's population. Rice is the staple food for most people in Asia but the grain consumes two to three times more water than wheat or maize. This poses massive problems for a region with scarce resources, with water already scarce in some major rice-growing areas in Asia. Currently, about 55 per cent of rice fields are irrigated and account for 75 per cent of production. It is projected that by 2025, the number of rice consumers will double to 4.6 billion.

Asian countries are getting good responses from the field trials of genetically modified rice, but the first commercial crop may be at least three years away. Field trials were going on in China, India and the Philippines and the governments were studying the benefits closely before taking the plunge. But it could be three years on the lower side and five years on the higher side to see the first genetically modified rice crop. Rice yields would have to rise at least one per cent annually over the next 30 years to keep up with an expanding population. IRRI projects the number of people eating rice will almost double to 4.6 billion by 2025. On the genetically modified variety of rice that is being currently tested in the Philippines, the feedback so far has been that the resistance to diseases is good and it will have an impact on the productivity.

However, a lot of anxiety in Europe is spilling over to Asia. The debate surrounding biotech grains has intensified, with non-governmental organizations mounting protests worldwide as they argue such crops pose health hazards. They help boost productivity and lower production costs in addition to boosting nutritional content. Earlier biotech giant Monsanto shelved plans to introduce the world's first biotech wheat it had developed over six years. Studies showed consumers and food companies were skeptical about embracing biotech wheat in their bread and cereals.

IRRI helps Bangladesh grow better rice

About 2,000 resource-poor Bangladesh paddy farmers have been trained to raise the crop sans use of insecticides and with reduced application of nitrogen fertilizer, but without lowering the yield in anyway. Taken up at the initiative of Manila-based International Rice Research Institute (IRRI), the unique experiment has brought financial benefits to paddy growers as they have saved money on inputs such as insecticides and fertilizers. Importantly, the success of the experiment is expected to set off a chain reaction.

Paddy is an important field crop for Bangladesh as the majority of the population eats rice. The landholding is fragmented. Rice production is in the 24-26 million tonnes range. Following its success, the experiment is being replicated within the country on a much larger scale. Close to 12 million farmers are engaged in paddy cultivation. Because of indigenous output trails demand, the country is forced to resort to imports at an enormous cost to the exchequer.

From 0.3 million tonnes in 2002, Bangladesh's rice imports jumped to 1.1 million tones in 2003. For 2004 and 2005, projected imports are 5 million tonnes each year. More important, lower production cost without any compromise on yields means higher farm income for growers and improved living standard. Not only financial gain, the experiment is bound to deliver ecological benefits too.

Reviving Red Rice Variety

Scientists in the northern Indian state of Himachal Pradesh are trying to revive an exotic Himalayan variety of rice ("red rice") that is on the brink of extinction. The "red rice" was traditionally grown in a few remote pockets along riverbanks in the Shimla and Kulu districts of the state. Besides being tasty, red rice made the Himalayan countryside picturesque. Villagers are worried that the production of this traditional grain has dropped because of the non-availability of new seeds, and rice blast, a fungal disease that is pushing the grain to extinction. In recent years, poor seed quality and diseases have affected the production of other traditional varieties of rice like *Chwartoo, Shanti, Ram* and *Javaeen.*

A team of scientists from Palampur Agriculture University visited the Pabbar valley in the Shimla district and interacted with farmers. The team has developed new varieties of the rice and distributed them to farmers. Although the yield has gone up, farmers say the taste does not match up to that of the traditional variety. They are now working on the new varieties so that they have the same taste, currently under research at Palampur University. If it is a success, they could consider marketing the rice in the international market, including in Bhutan, where similar varieties are grown. It is difficult to procure "red-rice" from farmers, unlike a decade ago when it was easily available in small towns. Producing this variety of rice is a highly labour-intensive operation and costs up to Rs. 40 kg.

Rice gene to enhance tolerance in other crops

A serious challenge today is to sustain and improve crop yields to feed the growing world population. Rice is a staple food in much of the world and hence increasing its production is of special interest. Though rice production has increased over the years, it will need to increase another 60 per cent by 2025 to feed the growing population. Traditional breeding strategies have been used to exploit natural genetic variation in improving crop varieties, but until now, very few plants showing enhanced tolerance to stresses and better yields have actually made it to the fields. Several genes have been reported to be up- or down-regulated in response to different stresses. These genes might generate products either directly involved in protection against environmental stress or that play a role in stress regulation. The first category would constitute genes coding for osmoprotectants, scavengers of reactive oxygen species, or stress proteins such as COR or LEA with an undefined mechanism of action. In the latter category would be genes that code for regulatory proteins such as transcription factors or components of signal cascades. These proteins would regulate the expression of a set of genes involved in stress.

The OSISAP1 gene was cloned via the differential screening of an *indica* rice cDNA library in an attempt to identify genes that show organspecific and/or stress inducible expression. OSISAP1 was expressed at a higher level in the root and the prepollination stage spikelet as compared to shoot. Further, expression analysis of OSISAP1 revealed that the gene is expressed in response to several abiotic stresses like cold, salt, drought, submergence, mechanical wounding, and heavy metals. The gene was overexpressed in tobacco under the control of a constitutive CaMV35S promoter to understand its function, and especially to determine whether the gene has a role to play in stress response. Transgenic lines were analyzed for cold, dehydration, and salt stress tolerance in the T1 generation. OSISAP1 could be a promising target for producing stress tolerant crops because it is inducible by different kinds of abiotic stresses and, upon ectopic over expression the transgenic show improved tolerance to cold, dehydration, and salt stress. It is quite possible that the gene may have a role in imparting tolerance to other stresses, which causes an increase in its transcription in rice.

Gene-altered rice

A handful of anti-biotech activists descended on Ventria Bioscience last week with an "eviction notice" and a moving van, bluntly inviting the Sacramento company that grows pharmaceuticals in rice to leave the state. Ventria's proposal to grow its novel product is scheduled for review again Tuesday morning by a rice industry panel in Yuba City. But the street theater signaled that the company's plans to ramp up production are catalyzing concerns about manufacturing drugs in food crops. This has provided a really graphic wake-up call. It's such a sci-fi thing.

Not just the activists are concerned. In Japan, the influential Rice Retailers' Association said it would seek a ban on California rice imports if genetically modified, or GM, rice is grown commercially in the United States. The industry group think it is practically impossible to guarantee no GM contamination in non-GM (rice). Californians also have taken notice. Many Sacramento Valley rice farmers are wary, even though Ventria promised to grow its rice only in counties where no commercial food rice is grown.

San Luis Obispo was one of 10 counties Ventria could target for its "pharma" crop, which has been engineered to produce two common human proteins, lactoferrin and lysozyme. The company envisions using them in anti-diarrheal treatments. After reading newspaper reports about the possibility of the novel crop in San Luis Obispo, an unsettled county

Board of Supervisors ordered a review of what it could mean. The county had no say in a plan that affects its top industry, farming. They should certainly have major involvement in what goes on here. At the state level, there is a request for an environmental review before the California Department of Food and Agriculture decides whether Ventria can ramp up production beyond its current test plots.

All are concerned that action on this is being contemplated before the potential environmental impacts have been adequately considered. Sher has yet to get a response. The agency would follow applicable environmental laws when it takes up the Ventria plan. That could be soon, if meeting of the 12-member rice industry panel goes smoothly. The panel, set up by state legislation to keep rice varieties separate, in March approved a strict set of procedures that would allow Ventria to become the nation's first commercial-scale producer of plant-made pharmaceuticals. The goal was to ensure the company's rice doesn't mix with food rice. Next, the plan went to the CDFA, which was inundated with more than 1,400 letters - many of them form letters, and virtually all of them wary about growing drug compounds in open fields.

In vietnam, rice is the web of life

It is befitting that the United Nations declared 2004 the International Year of Rice. Rice is a staple food for more than half of the world's population. It is the principal source of income for more than 1 billion people, most of whom are farmers.

The promotional year, under the auspices of the Food and Agriculture Organisation, hopes to encourage greater access to rice and increased production. It also aims to reduce hunger and poverty, and promote environmental preservation in rice-producing countries.

It goes without saying that this decision greatly interests Viet Nam, where 80 per cent of the population lives in rural areas and essentially survives on rice farming, and also where during the double rule of the Japanese and the French in 1945, a famine took a toll of 2 million lives. The *doi moi* (renewal) policy has put an end to the perennial food shortage and turned Viet Nam into the world's third largest rice exporter.

Six thousand years ago in what is now northern Thailand, rice grew like weeds before it was cultivated by man. Today, 90 per cent of rice is grown in Asia and its production feeds 40 per cent of the world's population. In Viet Nam, the first record of rice dates back to the

Mesolithic culture of Hoa Binh-Bac Son (10,000-8,000 BC). What is certain is that by the dawn of the Vietnamese identity in the valley of the Hong (Red) River in the first millennium of the Bronze Age (BC), rice growing had become culturally ingrained in this country, as well as in neighboring Southeast Asian countries.

Rice is the web of life in Viet Nam. In the Vietnamese language, it is translated into different designations: *lua* is the rice plant, *thoc* is raw and unhusked rice, *gao* is raw and polished rice, *com* is ordinary rice, cooked, while xoi is glutinous rice, steamed. In the old days, a woman who was unable to breast feed her child would give it rice porridge, and when it was old enough, she would feed it with chewed *com*. When a person dies, he is said to have taken *xoi*, probably because this type of rice is commonly part of the votive offerings for the dead.

Viet Nam practices both dry rice culture (in mountainous areas) and wet rice culture (in irrigated fields on the plains). The country has benefited greatly from measures proposed by the Green Revolution of the 1960s. These included greater productivity, like the use of high-yield seeds, mineral fertilisers, plant sanitary products, and improvements in irrigation. It also successfully put to use various short-stemmed plant varieties developed by the International Rice Research Institute in the Philippines that had the advantage of concentrating energy generated from photosynthesis on the ear and not on the stem of the rice plant.

In the countryside following the August Revolution of 1945, mutual aid groups were set up for farmers to help one another in production. When the resistance to the French ended in 1954, a land reform to return land to the tillers was conducted in the liberated North. In the 1960s, such household plots were regrouped into village-sized co-operatives. During the American war, these agricultural co-operatives were deprived of the local workforce of men and boys. The co-operatives filled the void left by the departing soldiers by providing rice, food and other labour to villagers and the families of soldiers. They shared the work collectively, with women taking a greater role in food production. After the war, unfortunately many co-operatives became ineffective because of bureaucratic management and the egalitarian distribution of produce. Gradually, the co-operatives became moribund: in the early 1980s many farmers refused to harvest co-operative fields.

The new policy of *doi moi* was instituted in 1986 to curb a prolonged economic crisis that lasted for many years, and to revive agriculture by giving farmers the full scope of production. The success was spectacular;

rice export in 1989 totalled 2 million tonnes and now the country ranks third in the world for that particular export line. For Vietnamese rice to have its place in the world market in this era of globalization, agricultural co-operatives should be reorganized in a way that suits the interests of farmers.

Vietnam implements seven year biotech development plan

Vietnam will be aiming to develop its biotech industry over the next seven years – with the refurbished biotech industry expected to deliver new plant varieties and animal breeds with increased productivity, quality and competitiveness and become a biotechnology leader by 2010. The biotech sector will also focus on developing artificial reproductive technologies, producing disease free plant varieties, and animal breeds, cleansing the aquaculture environment, and controlling epidemic diseases. Biotechnology is expected to generate jobs for about 700,000 rural workers, and the Ministry of Science and Technology in Vietnam hopes to train an additional 2,000 scientists between now and 2010. The ministry suggested that the government devise specific policies aimed at attracting foreign scientists to increase the professional capacity of the local biotech industry, and also in order to encourage Vietnamese researchers residing abroad to return to their homeland to work.

Speaking at a biotech conference held in Hanoi, Vietnam's Deputy Prime Minister Pham Gia Khiem called for a strengthening of training and international cooperation in the industry. He urged the industry to rationalize the management of biotechnology and increase the use of information technology. Laws to regulate intellectual property rights and genetic modification were currently being made in Vietnam. While the country has previously concentrated its biotech efforts on plant breeding, fertilizers and bio-pesticides, Vietnam is now edging towards a more systematic technology-based approach to biotech at the same time. With six national biotech laboratories already planned to open by 2006, the Vietnamese government is also making vast investments to generate opportunities for companies in the biotech-IT field.

Vietnam has already used advanced gene technologies to create novel vaccines and insect-resistant plants, and Vietnamese scientists are starting to study the cloning of animals. Facilities are being set up to store genetic material from a variety of plants, animals and micro-organisms, which will provide up to 500 species for biotech research use.

ACD agriculture ministers adopt joint initiative in Beijing

A two-day Asia Cooperation Dialogue (ACD) workshop in Beijing had attracted agriculture ministers or vice ministers from 20 countries. Participants agreed to cooperate in the areas of development policy, practical technology, sustainable development, and rural development and poverty alleviation. Chinese Vice Minister of Agriculture Zhang Baowen reportedly promised that China would organize two follow-up activities: an ACD agricultural policy forum to discuss development strategy and policy measures and to mark International Year of Rice, a rice-development workshop and technology exhibition.

Food and Agriculture Organization (FAO) of the United Nations declared that rice plays and would continue to play a crucial role in the sustainable agricultural development of the Asia-Pacific region. The release of the report coincided with FAO's annual Regional Conference for Asia and the Pacific, held in Beijing. The report was not optimistic, however, about the future of the international rice trade, which it projected to increase at a modest 1.5 per cent per year in the current decade to 29.3 million tonnes in 2010, much below the explosive growth of the 1990s. The report called for radical changes in rice-trade policy.

INGER provides viable options

A certain cooperative bank generates resources for agricultural development by pooling its member countries' assets. The countries deposit these assets without taking them out of circulation at home. India, the largest depositor, has withdrawn 10 times as much as it has deposited. Many countries, most recently Cambodia and East Timor, have made withdrawals without first making a deposit. This marvelous "bank" is the International Network for Genetic Evaluation of Rice (INGER), soon to celebrate three decades of sharing elite rice germplasm - seeds and the genetic material they contain – across Asia and the rest of the world. Called the International Rice Testing Network when the International Rice Research Institute (IRRI) and its national agricultural research and extension system (NARES) partners, INGER, launched it in 1975 has served as the recruiting office of the Green Revolution.

The main role of INGER over the years has been to assemble and distribute rice germplasm and to analyze, interpret and disseminate the results of varietal evaluation and use, both as breeding material and in farmers' fields. INGER receives the best rice varieties and advanced breeding lines developed by NARES, IRRI and three of its sister centers in the Consultative Group on International Agricultural Research (CGIAR): the West Africa Rice Development Association (WARDA) – the Africa Rice Centre; the International Centre for Tropical Agriculture (CIAT by its Spanish acronym); and, until it discontinued its rice-breeding programme in the mid 1990s, the International Institute for Tropical Agriculture (IITA). The INGER programme at IRRI assembles nurseries both for global use and to meet the special needs of Asian countries. INGER Africa, led by IITA from the mid-1980s to the mid-1990s and now by WARDA, establishes specific nurseries for Africa. INGER Latin America and Caribbean, at CIAT, has looked after the particular needs of that region, in cooperation with Fondo Latinamericano para Arroz de Riego, a public-private partnership for international research on rice.

Australian and New Zealand GM food labelling standard one of the most comprehensive in the world

A review of labelling of genetically modified (GM) food, conducted by Food Standards Australia New Zealand (FSANZ), has found that Australia and New Zealand have one of the most comprehensive labelling regimes for GM food in the world. The final report of the Review of Labelling of Genetically Modified Food, commissioned by the Australian and New Zealand Food Regulation Ministerial Council, is now publicly available.

Three years ago Australian and New Zealand ministers responsible for food agreed to mandatory labelling for GM foods. These requirements came into force in both countries in December 2001. They require any food, food ingredient or processing aid produced using gene technology and containing novel DNA and/or novel protein or having altered characteristics to be labelled as 'genetically modified'. As Australia and New Zealand were among the first countries in the world to introduce GM labelling, in August 2003, Ministers requested that FSANZ conduct a review to compare our GM labelling requirements with international practice. In Australia and New Zealand all foods produced using gene technology must be safety assessed by FSANZ before they can be sold. The labelling requirements for GM food are not about safety; they are designed to enable consumers to make informed choices about what foods they eat.

The review found that although Australian and New Zealand were among the first countries in the world to adopt mandatory GM food labelling, these requirements remain among the most comprehensive, both in scope and breadth of capture, of any country in the world. In Australia and New Zealand the majority of consumers welcome mandatory labelling of GM food so that they can make informed purchasing decisions. Consumers in other countries also hold these views. Two separate compliance surveys conducted by enforcement authorities in Australia and New Zealand and finalized in 2003 found a high level of industry compliance with the labelling requirements. Of the 168 products tested, all but one was considered to be compliant with labelling requirements. The non-compliant product was identified in the New Zealand survey and enforcement action was initiated with the product being recalled and the labelling rectified.

The surveys demonstrate that the labelling requirements can be effectively enforced using strategies which examine compliance plans and documentation held by manufacturers, and supplemented by product testing where appropriate. International regulations for the labelling of GM foods vary markedly from country to country. For example, the EU permits accidental contamination of foods with small amounts of unapproved GM commodities in the food supply while Australia and New Zealand does not permit any unapproved GM commodities for sale or use in the food supply.

U.S. expects biotech labelling stalemate to continue

The United States expects the issue of mandatory processed-based labelling of bioengineered foods to continue in "stalemate mode" at the Codex Committee on Food Labelling. Earlier it was hoped that the US could lay the issue aside, at least for a time. A work group appointed by CCFL chair Ann Mackenzie failed to agree last fall on how to handle the issue, but it refused to let the matter drop. The chair, and the (work group meeting) report, say there is no consensus to lay the issue aside. On the other hand, there is no consensus on going forward either.

Labelling of bioengineered foods has long been a bone of contention in Codex. Proposed biotech labelling guidelines have failed to advance beyond Step 3 in the eight-step approval process. Draft definitions of terms, which were approved by the committee but rejected by the full Codex Commission in 2001, are stuck at Step 6. Noting that the draft definitions of terms are at a more advanced stage of approval, it is added that we should not allow them to go forward until we have a clearer picture of what comes out of the substantive labelling issues. The draft definitions are not consistent with definitions supported by the United States and agreed to by the Japanese chair of the now-expired Codex Ad Hoc Task Force on Foods Derived from Biotechnology.

Europe introduces labelling laws

Europe has introduced stringent rules for the labelling of food that contains genetically modified organisms. But in most countries the labells will take months to appear – and questions remain about how they will be implemented. The rules, which are imposed by the European Union, are intended to aid consumer acceptance of genetically modified food in Europe. They may help to defuse a US complaint to the World Trade Organization (WTO) that Europe is unfairly blocking imports of transgenic food.

Food containing more than 0.99 per cent genetically modified ingredients must be clearly labelled as doing so, the rules say. If the ingredients are awaiting final approval as being safe to eat, that threshold falls on 0.5 per cent. This is the biggest piece of legislation in the food industry for 20 years, a firm based in Fairfield, Iowa, is offering to test food for its transgenic content. Britain, Germany and the Netherlands are expected to implement the regulations in stores within a few months, but other nations may take longer.

The rules require food to be tracked from its source through manufacture to the point of sale. Manufacturers and packagers will also have to test food directly for traces of genetically modified organisms. A network of laboratories set up and operated by the European Commission (EC) has developed a series of standard tests. The Institute for Health and Consumer Protection, part of the EC's Joint Research Centre in Ispra, Italy, has led the development of these tests, which use polymerase chain reaction technology to search for modified DNA. But the tests do not work with the refined products, such as oil or sugar, of some genetically modified organisms because they may contain no transgenic DNA, so figures for food containing these will depend on manufacturers' supply-chain records. Many retailers doubt that customers will buy food products labelled as genetically modified, and some refuse to stock them. Analysts are unsure whether the new rules will make any difference to consumer acceptance-or to the United States' complaint to the WTO.

FAO adopts new guidelines for risk assessment

New guidelines for determining if a living modified organism (LMO) poses a hazard to plants have been published by FAO. Some 130 countries adopted this unique international standard on how to assess the risks of LMOs to plants. With some LMOs there is a potential risk of introducing a gene that could cause a normal plant to become a weed. Internationally accepted guidelines will help countries to reduce the risks of releasing LMOs that are weedy and could seriously harm our crop and plant ecosystems. The guidelines also cover other LMOs that may be harmful to plants, such as insects, fungi and bacteria. The Interim Commission on Phytosanitary Measures, which adopted the Guidelines, is the governing body of the International Plant Protection Convention (IPPC). This international treaty helps to stop the spread of pests and diseases affecting plants.

The new guidelines will help countries assess the risks of LMOs and determine whether some should be considered as weeds or other organisms that damage plants. Their introduction could then be regulated in order to protect crops and ecosystems. The guidelines harmonize and standardize the way countries analyse risks that LMOs may pose to plant health. A country may now use the guidelines to determine which LMOs pose a threat and, if necessary, can subsequently prohibit or restrict their import and domestic use. This is of particular value to developing countries, which can now use the same risk analysis criteria as developed countries.

In the case of trade disputes concerning plant health, the World Trade Organization (WTO) refers to IPPC standards. Phytosanitary measures that conform to IPPC standards are deemed necessary to protect plant life or health. The IPPC, within its overall scope of preventing the spread and introduction of pests of plant products, covers LMOs as far as they are pests of plants; the Cartegena Protocol addresses, in general, the safe transfer, handling and use of LMOs, specifically focusing on transboundary movement.

Biotech firms abandon crop trials in UK

All the major biotechnology companies have abandoned trials of genetically modified (GM) crops in the UK this year, according to a report by *The Guardian* newspaper. Only one crop – a herbicide resistant GM pea that is being tested for drought resistance – has been given a license to be planted this summer. At the end of last month, biotech giant Bayer caused a stir by abandoning efforts to market its Chardon LL maize variety, which had recently received government approval. The lack of planting applications shows a dramatic change in the fortunes of GM technology, which remains unpopular with the public, the paper comments. The number of applications peaked at 159 in 2000-2001 (inflated by the government sponsored three-year trials of rape, sugar beet and maize) and then fell to 140 the next year, 42 last year and only one this year.

All the big companies - Novartis Seeds, Aventis CropScience and Bayer CropScience - have told the government that they will not grow any GM crops. Also the largest British research centers have stopped GM trials. The failure to test further varieties of crop is interpreted by industry watchers as despair at ever getting the technology accepted in Britain. The GM slowdown was a sign of how the companies were giving up. "It is reflected across the rest of Europe. Research is now being directed elsewhere to other ways of improving crops which do not involve GM.

(Sources: *Checkbiotech*, January, 24, 2005; *Business Line*, January 25, 2005; *Viet Nam News*, June 3, 2004; *Bridges Trade BioRes*, Vol. 4 No. 23, December 20, 2004; *Food Chemical News*, April 8-9, 2004; www.irri.org, June 29, 2004; *Asia-Pacific Biotech News*, Vol. 8 No. 7, 2004; *The Hindu Business Line*, July 30, 2004; *Business Standard*, October 9, 2004; www.checkbiotech.org, June 1, 2004; www.checkbiotech.org, June 1, 2004 ; *Viet Nam News*, November 21, 2004; *Rice Today*, Vol. 3 No. 4, October-December 2004; *Rice Today*, Vol. 3 No. 4, October-December 2004; *Nature*, Vol. 428, April 22, 2004; *Food Chemical News*, Vol. 46, April 5, 2004)
Agra Europe, April 16, 2004; *and Asia-Pacific Biotech News*, Vol. 8, No. 4, 2004

Document

We present herewith the FAO document reviewing the International Year of Rice and setting the agenda for future for wider dissemination.

International Year of Rice Follow-Up

The International Year of Rice (IYR 2004) was a powerful opportunity for the world community to implement global initiatives, including the Millennium Development Goals and the recommendations of the World Food Summit. Continued support from policymakers at national, regional and global levels as well as the donor community is needed in order to translate the achievements of IYR into concrete programmes and projects on sustainable rice development in rural communities for food security and poverty alleviation. The FAO International Rice Commission is ready to assist in the harmonization of efforts toward the development of efficient and sustainable rice-based production systems and the improvement of access to this vital food.

FAO Rice Programme beyond IYR 2004

The implementation of IYR in 2004 has already generated considerable support. The Italian Government provided initial funding support from under the framework of the project GCP/INT/933/ITA "Promoting, Coordinating and Implementing Observance of the International Year of Rice - 2004". The Government of Japan contributed an Associate Professional Officer to assist in the coordination of regional rice activities, conferences and seminars and recently approved the funding support to the dissemination of NERICA and improved rice technologies in Ghana and Sierra Leone. As requested by member countries, the IYR Secretariat developed two Regional Technical Cooperation Projects to help transfer specific technological innovations and promote capacity building for improved rice production in member countries.

Beyond 2004, the FAO Secretariat of the International Rice Commission will strengthen its capacity aiming at assisting member countries in the formulation and implementation of programmes and projects to help transfer specific technological innovations. The FAO Secretariat of the International Rice Commission will also continue to assist in capacity building for sustainable development and increase in rice production for food security and poverty alleviation in member countries. In the immediate future (2005-2006), the International Rice Commission will undertake the following major activities:

Publication of a book on "Rice is Life" to further raise the awareness of all stake-holders on the role of rice in food security, livelihood improvement, and sustainable production. The winning photographs in the IYR Global Contest will be used to enhance the message.

Preparation and submission of the report of the implementation of IYR 2004 to the UN General Assembly in July 2005 with recommendations on actions to be taken.

Organization of a Consultation Workshop on Rice Integrated Crop Management Systems in February 2005 in collaboration with the Ministry of Agriculture and Rural Development of Vietnam in order to review the progress made and to formulate guidance for effective development and dissemination of rice integrated crop management systems for rice production.

Organization of the 21st Session of the Commission in 2006 in collaboration with the Ministry of Agriculture of Peru to provide member countries with an opportunity to review the implementation of IYR, the issues and opportunities of sustainable rice production for reorientation of their national rice development programmes.

Providing technical guidance and support to the implementation of 17 projects on rice and rice-based systems in member countries.

The International Year of Rice 2004

Mission Statement: The International Year of Rice promotes improved production and access to this vital food crop, which feeds more than half the world's population while providing income for millions of rice producers, processors and traders. Development of sustainable rice-based systems will reduce hunger and poverty, and contribute to environmental conservation and a better life for present and future generations.

The Initiative for an International Year of Rice (IYR) came in 1999, when the International Rice Research Institute - responding to its members' growing concerns over the serious issues facing rice development - requested FAO's collaboration in having an IYR declared. This led to Resolution 2/2001 of the Thirty-First FAO Conference, which requested the United Nations General Assembly (UNGA) to declare the IYR. The Philippines, co-sponsored by 43 countries, submitted this request to the Fifty-Seventh Session of UNGA, which declared 2004 the IYR on 16 December 2002. The dedication of an International Year to a single crop was unprecedented in the history of UNGA. FAO was invited to facilitate IYR implementation in collaboration with other relevant organizations.

The theme of the IYR - "Rice is life"- reflects the importance of rice as a primary food source, and is drawn from an understanding that rice-based systems are essential for food security, poverty alleviation and improved livelihoods. Rice is the staple food of over half of the world's population. In Asia alone, more than 2 billion people obtain 60 to 70 per cent of their energy intake from rice and its derivatives; it is the most rapidly growing food source in Africa and is of significant importance to food security in an increasing number of low-income food-deficit countries. Rice-based production systems and their associated post-harvest operations employ nearly 1 billion people in rural areas of developing countries and about four-fifths of the world's rice is grown by small-scale farmers in low-income countries. Efficient and productive rice-based systems are therefore essential to economic development and improved quality of life, particularly in rural areas.

There are about 840 million undernourished people, including more than 200 million children, in developing countries. Improving the productivity of rice systems would contribute to eradicating this unacceptable level of hunger. However, rice production is facing serious constraints, including declining yield growth rates, natural resource depletion, labour shortages, gender issues, institutional limitations and environmental pollution. Enhancing the sustainability and productivity of rice-based production systems, while protecting and conserving the environment, will require the commitment of many parts of civil society, as well as government and inter-governmental action.

Many countries attach great importance to sustainable rice development, and there are a growing number of global initiatives aimed at promoting it. These include the Agenda 21 chapter on Sustainable

Agriculture and Rural Development (SARD) approved by 1992 Rio Summit; the 2002 World Conference on Sustainable Development; the 1996 Declaration on World Food Security and the World Food Summit Plan of Action; and the United Nations Millennium Declaration in 2000. Among the intergovernmental regulatory instruments that are of key importance for rice are those related to: food quality (CODEX Alimentarius); climate change; trade, and non- ariff trade barriers; biological diversity and the safe movement of modified living organisms; and ensuring equal access to and benefit sharing from plant genetic resources. Together with the IYR, these initiatives recognize that, in a world of increasingly interlinked institutions, societies and economies, it is essential that efforts are coordinated, responsibilities shared and participation included at all levels, from the local to the international.

"Rice is life": Aspects of rice-based systems

The IYR envisions rice as the focal point through which the interdependent relationships among agriculture, food security, nutrition, agro-biodiversity, the environment, culture, economics, science, gender and employment can be clearly viewed.

Rice Production: From its Asian homeland, rice is now cultivated in 113 countries and on all continents except Antarctica. It is grown in a wide range of soil moisture regimes, from deep flood to dryland, and in different soil conditions. Rice plays a variety of roles that are related to the following important aspects of food security as well as rural and economic development.

Nutrition: In the developing world as a whole, rice provides 27 per cent of dietary energy supply and 20 percent of dietary protein intake.

Agro-biodiversity Rice-based systems are hubs of biodiversity. They combine well with other agricultural production activities, such as the raising of fish or ducks on waterlogged rice fields, and the feeding of rice straw to livestock. In turn, ducks and fish feed on weeds and small aquatic organisms, while livestock help with transportation and land preparation, as well as providing organic fertilizer. Rice is also grown together with vegetables and fruit trees such as banana and coconut. Rice fields also host a wide variety of natural enemies that control harmful insects and pests. In these ways, rice-based systems provide great opportunities for improved nutrition, diversified agriculture, increased incomes and the protection of genetic and agricultural resources.

Water and land management: Rice is the only major cereal that can withstand water submergence and rice-based systems can make productive use of all the available water and land resources. Terracing allows cultivation on steep slopes, helps prevent soil erosion and landslides, controls floods, minimizes weed growth and generates water percolation and groundwater recharge, while submerged conditions enable organic matter to accumulate in soils.

Employment and income: Rice cultivation is the principal activity and source of income for about 100 million households in Asia and Africa, and several countries are highly dependent on rice as a source of foreign exchange earnings and government revenue. In addition, the threshing, milling, processing, market transport and cooking of rice helps support rural livelihoods. Other rural people generate income from producing, servicing and maintaining tools, implements and equipment for rice cultivation and post-harvest operations.

Gender: Women and men often develop different agricultural expertise and knowledge, and women play important roles in both rice production and post-harvest activities. However, women have less access to credit, farm inputs, marketing facilities, extension services and information, and often miss out on the benefits of improved rice cultivation at the field level.

Science: Improved technologies enable farmers to grow more rice on limited land with reduced need for water, labour and agro-chemicals. Genomic studies by public and private research laboratories have resulted in a comprehensive database of rice DNA, which is useful for breeders in developing rice varieties with higher yield and tolerance to pests and diseases. These varieties also have greater tolerance to abiotic stresses, such as drought and salinity, and higher nutritional value. Golden rice, a product of genetic engineering, has high vitamin content and is being evaluated by international and national research systems for its biosafety. The introduction of integrated crop management systems also helps increase efficiency while reducing production costs and negative environmental impacts.

Economic policy issues: For many decades, rice was one of the most heavily protected agricultural commodities. Since the 1980s, structural adjustment programmes and the 1994 WTO Agreement on Agriculture have changed this situation, and world rice trade is expanding strongly. However, urban consumers enjoy most of the benefits (especially lower rice prices), while small-scale, low-income farmers in developing countries bear the brunt of change. Developing countries now face the challenge of reaping the benefits associated with more efficient resource allocation, while alleviating the plight of small producers.

IYR: Challenges and opportunities

The IYR offers an important opportunity to use a collective approach towards resolving the increasingly complex issues that affect the sustainable development of rice and rice-based production systems. This has important technical, political, economic and social dimensions, including enhancing the role of rice in meeting human needs.

Improving food security and nutrition. Although rice is a rich source of energy and protein, it has an incomplete amino acid profile and contains limited quantities of essential micronutrients. Nutrition can be improved by better rice processing and cooking techniques, the use of rice varieties with high nutritional values, and the fortification of rice with vitamins and minerals (e.g. through applying food technology). Food security can be enhanced by promoting complementary crops, livestock and fisheries activities within rice-based systems. IYR can help countries develop the infrastructure to support the responsible utilization of biotechnology. It can also increase awareness of the need to support the diversity of rice varieties to reduce genetic vulnerability and to enhance both rice productivity and quality. Diversity in rice-based systems greatly contributes to rural income and complete nutrition in a more balanced diet.

Enhancing the productivity of rice-based systems. Sustainable rice development requires: i) genetic improvements for higher yield potential, e.g. hybrid rice; ii) better crop management techniques; iii) reduced post-harvest operations; and iv) the development of integrated production systems. It also requires improved national capacity, through training and information exchange, and the national-level transfer of safety-tested new technologies to the field.

Managing water resources: There is growing concern about the sustainability of global water resources. Water scarcity can be addressed by reducing the quantity of water required (through developing new rice varieties or improved irrigation systems) or by recycling water through multiple uses. The cultivation of rice in low-water regimes will lead to changes in water and nutrient management, cropping patterns and tillage practices. IYR can help improve understanding of the costs and benefits of water use in rice-based systems (e.g. the diverse life forms that such systems sustain). Technological developments and management interventions will also be required.

Environmental protection: Environmental concerns in rice production include indiscriminate use of pesticides, inefficient use of fertilizers, and emissions of greenhouse gases. At the same time, rice-based ecosystems host a wealth of biodiversity, and the majority of the planting material used by poor farmers is derived from seeds that they produce themselves and that represent generations of local genetic resources. IYR can spread awareness of the importance of preserving biogenetic and natural resources and can help stakeholders exchange ideas on environmental issues, challenges and opportunities.

Traditional rice-based systems as part of world heritage: IYR will raise awareness of the importance of benchmark rice-based systems, and will carry out activities to safeguard such systems and redress their erosion. The inclusion of outstanding rice-based systems in the multi-stakeholder, multi-agency Globally Important Agricultural Heritage Systems (GIAHS) Project represents a major opportunity. GIAHS is expected to lead to the creation of a new World Heritage for Agricultural Heritage Systems category under the World Heritage Convention.

The institutional context: More and expanded partnerships between government and non-governmental (including private sector) development and agriculture institutions are required in order to increase farmers' - particularly women farmers' - access to land, credit, information and new technologies and innovations. This will be a central challenge in many countries.

The challenge and opportunity for synergy: The overall challenge for rice-based systems is to identify and execute synergetic solutions for rice development, and these are possible only if decision-makers, technicians, farmers and civil society are well aware of the many factors related to sustainable rice production. In addition, sound policies on rice development depend on the harmonization of diverse policy instruments, which are often under the auspices of different ministries. IYR aims to be an "information broker" for increasing information exchange, technology transfer and concrete action among all levels in the rice production chain and across all nations, for a synergetic approach to rice development and the improved management of rice-based systems.

A conceptual framework for IYR implementation

The fundamental aim of IYR implementation is to promote and guide the sustainable development of rice and rice-based production systems, now and in the future. In order to meet this overarching goal, the IYR strategy focuses on the following intermediary objectives:

* increasing public awareness of the contributions that rice-based systems make to food security, better nutrition, poverty alleviation and livelihood improvement;
* increasing public awareness of the diversity and complexity of rice-based production systems, and the challenges and opportunities for their sustainable development;
* promoting and providing technical support to ensure the sustainable development of rice and rice-based systems at the global, regional, national and community levels;
* promoting the conservation and enhancement of rice-based products in order to derive economic, social, cultural and health benefits for the world's human population.

In achieving its objectives, the IYR is committed to the following guiding principles:

* a participatory, consultative, innovative and proactive approach that acknowledges the abilities and capacities of all stakeholders to make a valuable contribution to enhance the sustainability of rice-based production systems;
* recognition of the agro-ecological, socio-economic and cultural differences among rice-based production systems, as well as of the constraints to their sustainable development in different regions, countries and communities;
* coordination and harmonization of efforts contributions and participation among all stakeholders, through an agreed framework.

This IYR framework will consist of an organized system of UNGA-nominated partners at the global, regional, national and local levels. As the nominated lead organization, FAO has established an IYR Coordination and Implementation Unit to coordinate IYR activities at all levels.

The basis of the IYR implementation strategy is to engage the entire community in initiating combined and mutually beneficial actions that address the challenges associated with a sustainable increase in rice production. This is to be achieved through data collection and analysis; information dissemination via the multimedia; national, regional and global workshops, competitions and exhibitions; case studies; and the provision of technical support to member countries and farming communities. Reporting activities are particularly important and will include networking with stakeholders in order to monitor and advise on their activities, as well as producing a final report for submission to the Secretary General of the United Nations and to all stakeholders.

The IYR will establish a framework for enhancing the sustainable development of rice-based production systems, and will provide some of the means for achieving this. The IYR will utilize its resources efficiently by helping to establish and assist national IYR organizing committees; these committees can continue to develop the IYR vision beyond the Year. After 2004, FAO will collaborate with partners in establishing and assisting follow-up activities for medium and long-term sustainable development of rice-based production systems. Sustainability must continue to be pursued beyond the IYR.

Bio Web

Application of new technologies for rice research has attracted a major attention over the last couple of years. Several interesting initiatives have been launched in Asia and at other places. We provide here a select list of web sites giving details about some of such initiatives.

http://www.knowledgebank.irri.org

Rice Knowledge Bank is one of the world's first digital extension services for those who provide information and support for farmers (and their NGOs). It is also the first comprehensive, digital rice-production library containing an ever-increasing wealth of information on training and rice production. Taking the very latest and best ideas from the private sector's work in this area, the Rice Knowledge Bank is providing government extension officers, NGOs, and all others interested with access to rice knowledge and training information.

http://www.brribd.org

Bangladesh Rice Research Institute (BRRI) is a major component of the National Agricultural Research System (NARS) of Bangladesh, dealing with research and development in relation to rice production. Research for the development of new rice varieties and production technologies for the diverse ecosystems existing in Bangladesh are conducted at the BRRI main station at Gazipur and at *nine regional stations.* BRRI conducts research on all aspects of rice, demonstrate improved technologies to the farmers, train up extension personnel regarding modern rice technology, and to publish booklets and leaflets for rapid transfer of technologies.

http://www.philrice.gov.ph/

The Philippines Rice Research Institute (Phil Rice) undertakes, coordinates, and funds a national R&D programme for rice and rice-based farming systems. It also coordinates the national network of rice

R&D stations in the different agro-ecological regions of the country and provides timely information for policy formulation that will stimulate rice production, marketing and consumption.

http://ricecuttackindia.tripod.com/

India established a Central Rice Research Institute (CRRI), in 1946 at Cuttack, with 60 hectares of farm provided by the Government of Orissa which was later transferred to the Indian Council of Agricultural Research in 1966. The Mandate of the CRRI is to improve income and quality of life of rice farmers of India, particularly the resource poor rice farmers of rain fed ecosystem of eastern India.

http://irdc.ia.ac.cn/cistc/english/add/Detail.asp?class=14&id=21018&column=768

China National Rice Research Institute (CNRRI) is an integrated research institute of multi-disciplines with rice as its major research subject. It was established in Hang Zhou, Zhejiang Province as approved by the Chinese State Council in June 1981, and the inauguration was held in 1989. CNRRI is the largest agricultural research institute invested by the state since the founding of the People's Republic of China.. At present, it is under dual leadership of the Chinese Academy of Agriculture Science and the Zhejiang People's Government. CNRRI focuses on basic and applicable basic research with priority on solving significant scientific and technical problems in rice production. It is engaged in rice research at population, individual, tissue, cell, and molecular levels.

http://www.drrindia.org/

The Directorate of Rice Research (DRR), formerly All India Coordinated Rice Improvement Project (AICRIP), was established by the Indian Council of Agricultural Research (ICAR) in 1965 with its national headquarters at Hyderabad. DRR in its 37th year of useful existence has contributed significantly in overall rice production front which has ensured food security for the country.

http://www.rice.ac.lk/

Rice Research and Development Institute (RRDI) in Sri Lanka plays a major role in the country's rice sector by releasing new high yielding rice varieties and introducing improved rice production and protection technologies to help farmers realize the yield potentials of the varieties that they grow. The research and development programmes at RRDI focuses on increasing farm productivity, reducing cost of production and improving grain quality of rice. Efforts were made to develop techniques that will help increase rice plant's nutrient use efficiency. A need base fertilizer application method is being tested. This would help maximize effectiveness of fertilizers applied and reduce cost of production. Other agronomic practices to reduce production costs are being tested.

http://www.irri.org/ARBN/

The Asian Rice Biotechnology Network (ARBN) was established at IRRI in 1993 to help national agricultural research systems (NARS) institutes in Asia to apply biotechnology tools to improve rice production. ARBN, through its training and collaborative research activities, provides a unique mechanism for NARS institutes to access relevant knowledge and biotechnology tools to solve their rice production problems.

http://www.asiariceusa.org/

The Asia Rice Foundation USA (ARFUSA) organized in 1999 by a group of people with roots in Asia supports work toward a world that can feed itself, treasures the rich heritage of its rice cultures and values its rice growing land as a precious commodity to be shared with future generations. ARFUSA makes study and travel grants to help young people learn about rice in Asia by going to Asia to study aspects of rice production, marketing, consumption, policy or to create art or interpret culture related to rice in Asia.

http://www.medrice.unito.it/

MED-RICE (Inter-regional Co-operative Research Network on Rice in the Mediterranean Climate Areas) was created in 1990 by FAO with support from the Regional Office for Europe (REU), Regional Office for the Near-East (RNE) and the Crop and Grassland Service (AGPC), with collaboration from INRA and National Agricultural Research Centers (NARS). This network is part of the inter-regional and regional networks on rice and field projects, and it is supported by the International Rice Commission (IRC) and the Rice Development Programme (RDP) of FAO. The objective of MED-RICE is to promote scientific exchanges among rice scientists in the Mediterranean area and in the other world regions with a Mediterranean climate.

Bio Stats*

This column puts together some empirical evidence and relevant statistics to show importance of rice in Asian economies.

Rice remains the staple food of more than half of humanity. However, rice yields would have to rise at least one percent annually over the next 30 years to keep up with an expanding population. IRRI projects the number of people eating rice will almost double to 4.6 billion by 2025. On the genetically modified variety of rice that is being currently tested in the Philippines, the feedback so far has been that the resistance to diseases is good and it will have an impact on the productivity. An international team of scientists from 10 countries had completed the sequencing of the rice genome. Scientists had completed mapping some 370 million out of 390 million base pairs or 95 per cent of the genome — with an accuracy of 99.99 per cent. This development is expected to lead to the acceleration of research on rice and the potential development of new varieties of rice.

In Asia, where 90 per cent of all rice is grown and consumed, more than 2 billion people obtain 60-70 per cent of their calories from rice. More than half of the world's 1.3 billion poor are Asian rice farmers and consumers, and Asia's poorest - urban slum dwellers and rural landless - still spend up to 40 per cent of their income on rice. Among the top ten exporters of rice in the world six are from the Asian region. Thailand (8 million. tonnes), Vietnam (4 million. tonnes) and India (4 million. tonnes) are the top three rice exporters in the world (Table 1). Incidentally, the top three importers of rice are also from Asia viz. Bangladesh, Philippines and Indonesia. As table 2 shows the area under

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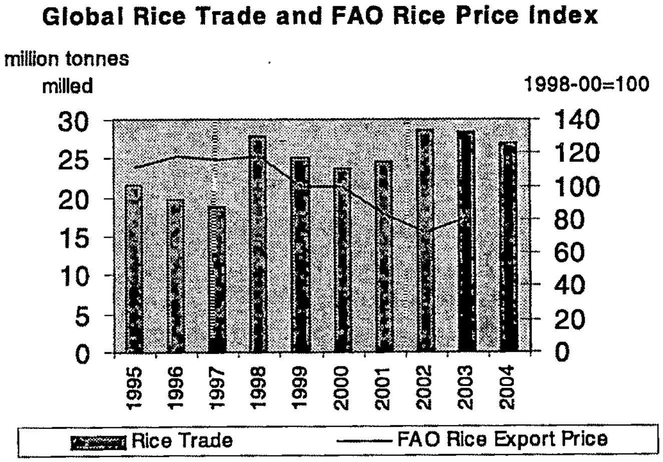
* Prepared at RIS Biotechnology Unit.



modern rice varieties in major economies of Asia is considerably high. In major exporters like Thailand (30 per cent), Vietnam (92 per cent) and India (76 percent) is under rice. Even among major importers the area under modern rice varieties is considerably high for instance, in Bangladesh (65 percent), Indonesia (84 per cent) and Philippines (96 per cent).

According to the trade estimates available from Food and Agriculture Organization (FAO) of the United Nations rice market monitor, the contraction in rice trade reflects smaller expected deliveries to Bangladesh, Indonesia and the Philippines. Much of anticipated drop in trade would also reflect smaller sales b exporters in India, as well as Vietnam and the United States, as some of their traditional markets are forecast to shrink. Supply constraints might also result in lower (food aid) shipments by Japan and the Rep. of Korea.

Table 1: Top Ten Rice Exporters in 2003

Country	Million MT
Thailand	7.75
Viet Nam	4.25
India	4
US	3.4
China	2.25
Pakistan	1.1
Myanmar	1
Uruguay	0.65
Egypt	0.4
Argentina	0.35

Source: AS&PM Magazine, Vol. 11 No. 1, Jan/Feb. 2004

Table 2: Rice Area under irrigation and modern varieties in Major Asian Countries

Country	Area under Rice ('000 Ha.) 1998	2002	% rice, area irrigated 1998	% rice area under modern varieties, 1998	Paddy yield (t/ha), 2001
Bangladesh	10116	11059	42	65	3.58
China	31572	28177	99	98	6.26
India	44598	44622	50	76	3.08
Indonesia	11716	11500	78	84	4.23
Myanmar	5459	6200	30	76	3.42
Nepal	1506	1517	49	74	3.17
Philippines	3170	4046	70	96	3.14
Sri Lanka	829	715	72	96	3.83
Thailand	9900	9990	20	30	2.72
Vietnam	7363	7485	85	92	4.15

Source: FAOSTAT 2002 and FAO Production Yearbook, various volumes

Announcement

Asian Biotechnology and Development Review

Vol. 8 No. 1 November 2005

Special Issue on

Biotechnology's Expanding Frontier: Biosecurity and Biosafety

Guest Editor: Dr Edgar Da Silva

Intellectual Property Rights in Plant Biotechnology: A Contribution to Crop Biosecurity.
K. Malik (Pakistan Agricultural Research Council, Islamabad, Pakisatan) and Yusuf Zafar (National Institute for Biotechnology and Genetic Engineering, Faisalabad, Pakistan)

The Impact of Biological Warfare and Bioterrorism on Biological Diversity with some relevance to Asia and the developing world
J. P. Dudley, (Institute of Artic Biology, University of Alaska-Fairbanks, Alaska, USA) and M. H. Woodford (Working Group on Wildlife Diseases, Office International des Epizooties -OIE, Portugal)

Strategies of Preparedness Against The Threat of Biological Warfare and Bioterrorism in Asia' with some relevance to Southeast Asia and the developing world
S. Plianbangchang (WHO-SEAR, India)

The Argentinean Experience : Enhancing Biosafety in Developing Countries through Good Laboratory Practices
Nidia Lucero (National Institute of Microbiology "Carlos Malbrán", Buenos Aires) and Faustino Siñeriz (Vice Rector for Science and Technology Universidad Nacional de Tucumán, Tucuman, (Argentina)

Ensuring Biosecurity and Biosafety through Biopolicy Mechanisms: Reduction and Elimination of the Threats of Bioterror and Biowar
Ronald Atlas, (University of Louisville, Louisville (USA)

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Training on Plant Tissue Culture

An international training course on plant tissue culture and transformation techniques will be held at the Agricultural Genetic Engineering Research Institute (AGERI) in Giza, Egypt on April 2-13, 2005. It is sponsored by AGERI, Academy of Scientific Research and Technology (Egypt), and the Centre for Science and Technology of the Non-aligned and other Developing Countries (India). The training course is open to participants from developing countries. For more information, contact Prof. Arun P. Kulshreshtha, Director, Centre for Science & Technology of the Non-Aligned and Other Developing Countries (NAM S&T Centre), Core 6A, 2nd Floor, India Habitat Centre, Lodhi Road, New Delhi – 110003, India. His email address is apknam@gmail.com.

Announcement

The New Asia Forum

RIS has been supporting the process of regional economic integration in Asia with its studies and research. Besides its pioneering contribution to the process of economic integration in South Asia, it has been supporting the ASEAN-India economic partnership. It has been developing proposals of a broader pan-Asian economic integration as a part of a research programme supported by the Sasakawa Peace Foundation. As its most recent initiative, the RIS has set up the New Asia Forum as a dedicated network of think-tanks in Asia devoted to assist this process of regional integration and thus help in building a New Asia with ideas. The *New Asia Monitor*, as a newsletter of the Forum, seeks to disseminate the news, viewpoints and information about resources among the policy circles and think-tanks to promote the cause of regional economic integration. The Forum is setting up a dedicated website www.newasiaforum.org as the melting pot for all the relevant information and resources on the subject.

Feedback and contributions are invited from all concerned.

Entrepreneurship Development Institute of India (EDI)

EDI, a national resource institute in entrepreneurship education, training and research located at Ahmedabad, has launched Post-Graduate Diplomas in Management of Non-Government Organizations (NGOs) and Post-Graduate Diploma in Business Entrepreneurship and Management.

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2. ABDR is multi disciplnary journal. Please explain technical details in simple words for the benifit of non-technical readers.
3. Use 'z' in '-ize' '-ization' words; e.g., 'civilize', 'organization'. Use British spellings rather than American spellings. Thus, 'labour' not 'labor'.
4. Use figures (rather than world) for quantities and exact measurements including percentages (2 per cent, 3 km, 36 years old). In general descriptions, numbers below 10 should be spelt out in words. Use thousands, millions, billions, not lakhs and crores. Use fuller forms for numbers and dates— e.g., 1980-88, pp. 200-202 and pp. 178-84.
5. Specific dates should be cited in the form June 2, 2004. Decades may be referred to as 'the eighties'. Spell out 'the twentieth century', etc.

References: A list of references cited in the article and prepared as per the style specified below should be appended at the end of the article. Reference must be typed in double space, and should be arranged in alphabetical order by the surname of the first author. In case more than one work by the same author(s) is cited, then arrange them chronologically by year of publication.

All references should be embedded in the text in the anthropological style – for example '(Hirschman 1961)' or '(Lakshman 1989:125)' (Note: Page numbers in the text are necessary only if the cited portion is a direct quote)

Citation should be first alphabetical and then chronological – for example 'Rao 1999a, 1999b'.

More than one reference of the same date for one author should be cited as 'Shand 1999a, 1999b'.

The following example illustrate the detailed style of referencing:

(a) **Books:**
Hirschman, A. O. 1961. *Strategy ofEconomic Development.* New Haven: Yale University Press.

(b) **Edited volumes:**
Shand, Ric (ed.). 1999. *Economic Liberalization in South Asia,* Delhi: Macmillan.

(c) **Articles from edited volumes:**
Lakshman, W. D. 1989. "Lineages of Dependent Development: From State Control to the Open Economy in Sri Lanka," in Ponna Wignaraja and Akmal Hussain (eds): *The Challenge in South Asia: Development, Democracy and Regional Cooperation.* pp. 105-63. New Delhi: Sage.

(d) **Articles from Journals:**
Rao, M.G., K. P. Kalirajan and R. T. Shand. 1999. "Convergence of Income across Indian States: A Divergent View". *Economic and Political Weekly,* 34(13): 769-78.

(e) **Unpublished Work:**

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- Patenting of Biotechnological Innovations
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- Challenges of Agro-Biotechnologies, Intellectual Property Rights and Globalization
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Asian Biotechnology and Development Review

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Editorial

IPR, Biotechnology and Biodiversity: Issues and Options before Developing Countries

The conclusion of Uruguay Round of GATT Negotiations that included an Agreement on Trade related Intellectual Property Rights (TRIPs) was a major step in terms of establishing a legally binding international intellectual property protection regime. During the Negotiations there was an interesting debate about the scope of patenting being extended to life forms. The sharp differences between the European Union and the United States led to the inclusion of a provision enabling a review of Article 27.3 (b) after four years of TRIPs coming into force, that is by 1999. This Article basically allows national governments to exclude certain inventions from the patent regime especially ones based on plants, animals and 'essential biological processes', including micro-organisms and non-biological and micro-biological processes. During the review process the scope of the debate expanded considerably. At the Doha Ministerial the developing countries also joined the debate. As a result, the issues related to indigenous knowledge system (IKS) and access and benefit sharing (ABS) were also included. As a result the Doha Development Agenda (DDA) (Paragraph 19) provides for the relationship between the UN Convention on Biological Diversity (CBD), which explicitly acknowledges IKS and ABS and seeks to look into the relationship between TRIPs Agreement and the CBD.

In this debate several developing countries have contributed through their submissions issues including like biodiversity and indigenous knowledge system and thus have expanded the scope of the debate itself. In between, the WIPO General Assembly also established an Inter-governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The conclusion of

International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) under the aegis of FAO further encouraged protection and promotion of farmers' rights and indigenous knowledge system.

However, one finds that the advances in agricultural biotechnology to some degree are paralleled by enhancement in the IPRs under TRIPs and at times in addition of TRIPs as well. This has brought under sharp focus the optimal patent scope and its coverage. This is now being discussed at length in the TRIPs Committee and the debate is largely around patentability and non-patentability of plant and animal inventions and the protection of plant varieties. In fact the TRIPs Agreement introduce the option of an "effective sui genesis" system for the protection of plant varieties.

The Checklist of issues submitted to WTO by Brazil, Cuba, India and Peru among others is a recent example of the kind of documents that are needed at this stage to delineate the concept of disclosure requirements and related issues so as to bring out the negotiating process from the current state of 'status quo'. The Switzerland proposal of making disclosure requirement an optional one under the national legislation rather than a mandatory provision at the international level may be explored for further facilitating the movement of the debate. The African group wants the TRIPs agreement to prohibit patenting of all life forms, including micro-organisms and wants *sui generis* protection for plant varieties to preserve farmers' rights. The US position is closer to that of Switzerland in the sense that the US proposal argues for national legislations to address CBD objectives on access to resources, traditional knowledge, benefit sharing.

In case of India at least some of these objectives have been included in the national legislations and guidelines. However given the emerging trend of free trade agreements across various countries and the IPR provisions in them, it is important that one looks into the IPR regime beyond the TRIPs framework as well. One may find this trend completely opposed to the spirit and objective of Article 7 of TRIPs. The objective of TRIPs as stated is "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". Here we briefly mention three broad trends in the patent regime important from the standpoint of the developing countries in context of their access to biotechnology per se.

Moving from PVP to Plant Patents

In recent past, plant variety protection (PVP) and the patents have emerged as two important forms of intellectual property rights. In context of developing countries, PVP has been there for some time but patents for plants is a recent phenomenon. Both patent and PVP provide exclusive monopoly rights over a creation for commercial purposes over a period of time. A patent is a right granted to an inventor to prevent all others from making, using, and/or selling the patented invention for 15-20 years. The criteria for a patent are novelty, inventiveness (non-obviousness), utility, and reproducibility. Although patents were designed for industrial application, with biotechnology, patent offices now grant patents on microorganisms and, in some countries, on all life forms, which has become a major concern as these countries are now entering in FTAs with IPR provisions much more stringent than TRIPs.

It is worth recalling that the intellectual property regime for plant variety protection emerged with a strong commitment for larger public interest in mind. The whole provision for compulsory licensing was introduced with this intention only. Under the provision of compulsory licensing, a holder of plant breeders' right, can neither refuse any applicant nor can offer unreasonable terms for access. Plant variety protection has worked well as a mechanism to promote the interests of the plant breeders for developing new varieties through giving them proprietary rights on the one hand and as custodians of public rights of access and use of genetic material on the other hand. PVP gives patent-like rights to plant breeders. What gets protected in this case is the genetic makeup of a specific plant variety. The criteria for protection are different: novelty, distinctness, uniformity, and stability. PVP laws can provide exemptions for breeders, allowing them to use protected varieties for further breeding, and for farmers, allowing them to save seeds from their harvest. In plant breeding, thus PVP is the weaker sister of patenting mainly because of these exemptions. Plant variety right also encourages cross licensing between a holder of PVR and a holder of a patent. Under the breeders' exemption of plant variety rights anyone may use protected material for breeding purposes.

However, the patent regime does not reciprocate this. Moreover, the growing usage of much more stringent instruments such as Utility Patents to protect biotechnological advances is another major concern.

Utility Patents

In the US the extension of IPR's to new plant varieties and biological inventions, including the development of biotechnologies, has stimulated private companies to invest in plant breeding. The Plant Patent Act of 1930 and the Plant Variety Protection Act (PVPA) of 1970 established plant breeders' rights for new plants and plant varieties. In 1980, a Supreme Court decision *(Diamond v. Chakraboarty)* authorized the use of patents for biological inventions, specifically microorganisms. However, several recent decisions by the Patent and Trademark Office have further broadened the use of patents for plants and have created space for Utility Patents in plants (ex parte Hibberd in 1985) and animals (ex parte Allen in 1987). Utility Patents are for any, "new and useful process machine, manufacture, composition of matter or any new and useful improvement therefor." Utility Patents can protect all the parts of the plants including genes, seeds, physiological and physical traits. Utility Patents have a larger coverage than PVPs in the sense that they cover not just a single variety as in PVP but also all other varieties having same traits and functional properties. Further, in Utility Patent not only is a single claim allowed, it also provides protection for covering plant parts including flowers, fruits and cuttings, etc. Apart from this, protection is not dependent on whether the plant is sexually produced or asexually produced. The share of Utility Patents among all other IPR instrument has gone up with the highest growth rate. Apart from plants now it covers research tools as well which in a way proposes to foreclose options for late comers in the technology race.

Patenting of Research Tools

One of the major trends in patenting which is emerging in US patent system is their broad nature. This is also one of the features as mentioned in the US-Singapore FTA. At times, it even encompasses research tools necessary for further downstream research and development. Some of the research tools, patenting of which have attracted attention are expressed sequence tags (ESTs), restriction enzymes, screening systems, technique related to DNA sequencing and single nucleotide polymorphisms (SNPs). As these research tools by definition have the power to control the downstream research of pharmaceuticals, they can wield an extremely large influence when patented.

A related problem is that of broad patenting which has actually grown over the years. For instance, Agracetus patent on all transgenic cotton (US patent 5, 159, 135) or similar patents on all transgenic soybean. Some of these patents are subject to reexamination or litigation to determine their validity. Similarly, a new US patent awarded to Monsanto in 2001, giving an exclusive monopoly right on crucial method identifying modified plant cells in laboratory. US Patent No. 6, 174, 724 covers all practical methods of making transformed plants that employ antibiotic resistance markers. The technique has been used in virtually all commercial GM crops. An earlier patent granted to another major US firm, Syngenta, covered a marker, which enables plants cell transformation and selection without the use of antibiotic resistance marker. This technology was first developed in a very small firm, Danisco in Denmark. This company sold the patent to Sandoz in 1998, which later became Novartis, which in 2000 became Syngenta.

Present Issue

In this issue of *Asian Biotechnology and Development Review*, we take a stock of this debate with an eminent panel of contributors from academia and policy world. Dr. K.K. Tripathi discusses the contours of biotechnology patent regime and its implications for India while Prof. Pranav Desai and Dr. Balakrishna Pisupati have linked up the debate with the wider developmental concerns especially in context of CBD and provision for plant variety protection. Prof. Dinesh Abrol and Dr. Malathi Lakshmikumaran have discussed at length the latest bill passed by the Indian Parliament amending Indian Patent Act 1970 and its implications on the biotechnology sector. Dr. Anitha Ramanna has analysed the current debate on access to technology and proliferation of illegal Bt cotton.

The usual columns of the journal also have a focus on IPR and licensing related issues. The Bio Stats presents brief comparative analysis of trends in biotechnology patents in major economies while in the Document section we provide OECD draft guidelines for licensing of genetic inventions, which at present is open for discussion.

Biotechnology and IPR Regime: In the Context of India and Developing Countries

K.K. Tripathi*

The word 'biotechnology' was actually coined early in the 20th century by an agricultural engineer from Hungary, named Karl Ereky, who explained it in such a way that the technology which include all such work by which products are produced from raw materials with the aid of living organisms. Subsequently, over the period, the definition of biotechnology acquired a confusing status due to various interpretations. The first official broad definition given by the US Office of Technology Assessment which states that "biotechnology, broadly defined, includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses" is also considered now void. In the broadest sense, the term "biotechnology" encompasses techniques applied to living organisms and parts thereof to produce, identify or design substances or to modify organisms for specific applications. Thus there may be many definitions of biotechnology as it is highly multidisciplinary involving almost all areas of science or to say, biotechnology combines disciplines like genetics, molecular biology, biochemistry, embryology and cell biology, which are in turn linked to practical disciplines like chemical engineering, information technology, and robotics.[1]

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Biotechnology can be traced back to various stages of its development. The first generation biotechnology can be based on the traditional knowledge in various tribes like preparing fermented foods, medicinal distillates, etc. Second generation of biotechnology may be considered when the utilisation of micro-organisms started on industrial scale during the Pasteur era which involved mass production of alcohol, fermentation of antibiotics, development of classical vaccines like for cholera, typhoid, yellow fever, etc. This generation can be considered as the longest one as the mass production of vitamins, amino acids, organic acids as well as plant tissue culture and animal breeding methods were also developed. The third generation of biotechnology can be called as "modern biotechnology" when the rDNA techniques, hybridoma technology, polymerase chain reaction (PCR) and cloning methods emerged during post-Second World War advances in molecular biology. The fourth generation of biotechnology would see further advances where interdisciplinary techniques like information technology and nano-technology would get involved in further advancement of this discipline, especially utilising the bioinformatics, which is the foundation of modern biotechnology. Rapid advances in information technology, particularly in the area of bioinformatics, have played a critical role in breakthrough applications of modern biotechnology in medicine and agriculture. Bioinformatics, broadly defined as the use of computers to handle biological information, has made possible the "genomic era". Bioinformatics provides the computer tools and databases to search, store, analyze and compare these data and to use them to develop, among others, safer and more effective medicines as well as higher yielding, more stress-resistant crops that have the potential for accelerating human development. However, as the *Human Development Report 2001* points out, this potential cannot be realized unless two conditions are met: First, that the modern biotechnology has to be utilized to address the key health and agriculture challenges facing poor countries. Second, modern biotechnology has to be utilized through a systematic approach that allows potential risks to human health, environment and social equity to be effectively assessed and managed.

The modern biotechnology, which is a late 20th century phenomenon, is the result of scientific advances that go well over a century. With the advent of modern biotechnology, the innovation in commercial biotechnology has been taking place the world over. However, the USA has pioneered the commercial biotechnology and can be called as the world leader due to various reasons. The other successful commercial biotech countries are Japan and Europe especially UK, Germany and France where the industries have enjoyed the benefit of ground breaking research carried out in universities and other public funded research institutions. Biotechnology and genomics have created enormous commercial opportunities in the area of healthcare, agriculture, environment and industrial products.

In the past one and half decade, India has shown excellence in scientific performance as evidenced by number and quality of publications made each year in international journals with the research leads on cover pages and various citations of Indian authors, but its technological and commercial performance is low as indexed by the number of patents issued per unit of investment made in R&D. There is considerable debate going on the IPR issues since India acceded to PCT, but still there is lot to be done in the awareness generation on the IPR issues. In the light of India's adoption of the recent Patent Amendment Bill of 2005, the product patent would be enforced. Further, the ongoing and preparative negotiations under GATS, especially for the R&D service sectors in general and biotechnology R&D, in particular would have a major impact on the biotech business of India and the other developing countries.

Biotechnology R&D and IPR Issues

The ownership and exploitation of intellectual property rights are the key factors in determining the success of any technological innovation introduced in the market that provide the means for technological progress to continue, to be made and thereby support the competitiveness of industry of the country. IPRs make it possible to develop strategies for dissemination and transfer of technologies in such a way, which may provide maximum societal benefits. It is a well-known fact that a country's economic and social success is utmost when different members of society have a common understanding, clear division of labour and responsibility with a common understanding for the shared societal values. The efficient management of IPRs is thus crucial in providing the right incentives for continuing technological innovations. The IPRs are thus helpful for new business opportunities and for value adding knowledge-based industry. It is high time that India rapidly adapts to the challenges posed by a continuously evolving technological environment of the world.

The regulatory mechanisms in IPRs have their own problems in the coming scenario of emerging technologies especially in biotechnology. The regulatory reform-initiatives are further required to streamline and sort out the problems in the new frontiers of IPR system. This would give further competitiveness in other significant economic sectors involving copyright, geographical indications, right to information to the society, patenting, etc. The patenting of new technologies, in the presently highly competitive environment provides the most robust system in the IP protection. Nonetheless, the biggest problem, which can be mentioned, is the copying of technologies that is becoming more and more frequent with the emergence of new technologies. For example, 60 per cent of all patented innovations are imitated on an average within four years; the ratio of imitation time to innovation is on an average of 70 per cent; the ratio of imitation cost to innovation cost is on an average of about 60 per cent. This is the reason with the advent of new technologies many corporate houses decide to protect their product/process by other methods and the most common is "non-disclosure" or not to protect their IP where the new technologies have a very short span of life cycle. The most common example of non-disclosure is the case of Coca-Cola and Pepsi who have never disclosed their formulations to anyone till today. At the same time the innovative industries try to keep finding better ways to protect their IP.

Paradoxically, we are in a situation today when the market requirements drive the industry to focus on short-term results while competitor nations are making significant investments in science and technological innovations for long-term benefits. There is a strong requirement for the management of culture, which could stimulate an understanding for research related IP issues. In the coming scenario of new technologies, a number of corporate bodies have started their own R&D activities and the competitiveness of the industry is largely determined by their ability to capture the economic benefits of scientific and technological innovations through knowledge driven technologies in general and biotechnology in particular. The advent of new technologies has not only given enormous benefits to society but has also raised a number of issues in the protection of the intellectual property. Intellectual Property Rights (IPR) on inventions in biotechnology have become a controversial topic of discussion in present years, as such inventions cut across issues related to science and technology policies, ethics and economics, etc. These issues are also directly related with the complexities of international trade. With the use of modern biotechnology many complex issues have spurred up in the IPR regime in general and patenting in particular. Several issues are indeed complex. Since the inventions in biotechnology cut across various aspects related to science & technology polices, polity of international trade, economic and ethical issues, the business methods in biotechnology have gained more complexity. Why do we have to familiarize ourselves with the science and issues surrounding modern biotechnology? There are at least two reasons. The first has to do with the potential benefits that modern biotechnology offers to humankind. The second reason why the knowledge of biotechnology is important is that with more biotechnology-derived products being placed on the market, chances are that these products will find their way into most countries, even those that do not use biotechnology for commercial purpose, but have to pay heavily due to strong IPR protection. A government needs to be familiar with modern biotechnology if it is to effectively regulate biotechnological products and ensure the effects, adverse if any, on the environment, human health, and social structures are properly managed, if not avoided. The European Commission (2002) refers to modern biotechnology as the "next wave of the knowledge-based economy" after information technology, and the "most promising of the frontier technologies."

However, developing countries should remember that the institutional and economic environment within which modern biotechnology R&D is being conducted differs significantly from that of Green Revolution technologies. The latter was essentially the prerogative of public research institutions and philanthropic foundations. In contrast, the application of modern biotechnology to agriculture is a competitive, commercial endeavor in which powerful private sector interests compete. Multinational companies in the seed, agricultural, chemical, pharmaceutical and food-processing industries play a major role in biotechnology research. Also, as a result of mergers and acquisitions in the past years, the development of new biotechnology applications in agriculture has become increasingly concentrated in the hands of a few companies. The dominant companies that currently operate within the global markets are Monsanto, Syngenta and Pioneer Hi-Bred. The Food and Agriculture Organization has pointed out that current transgenic crop releases are still "very narrow" in terms of crops and traits and thus have yet to address the special needs of developing countries. While some 200 crops are currently under field testing in developing countries and other crop-trait combinations are being investigated, focusing mostly on virus resistance, crop quality, and in some cases, tolerance to abiotic stresses, many crops (e.g., vegetables) and traits (e.g., drought- and aluminum-resistance) important to developing countries are still almost entirely neglected. There is a strong public perception that privatisation of intellectual properties may have negative impact in all developing countries on their agriculture and healthcare sectors followed by concerns in regional food security. At present biotechnology is widely used for the manufacture of therapeutic recombinant products, diagnostic devices in animal and human health sector, genetically modified products in agriculture sector, cleaner methods of fermentation based products for industrial use, production of microbial consortia for the efficient decontamination of environment, etc. The coming scenario would further see many more new and emerging products and processes like gene therapy, creation of artificial organisms, construction of artificial genes, and many unknown things, etc.

The next two years would witness how the developing countries would deal with the definitions of patentable microorganisms, protection of other living substances, distinctions between discoveries and invention, ethical issues in biological inventions, and in the provisions for making deposits for patentable biological materials. Genetic resources are the properties of the sovereign States to which they are indigenous. Future accessions of such resources would require consent from the States. The Convention on Biological Diversity (CBD) promulgates ensuring conservation and sustainable use of biological diversity, and fair and equitable sharing of benefits from their utilization. Supply and exchange of biological materials are expected to move across the national boundaries through the material transfer agreements on the basis of authorized, mutually agreed terms among States, and subject to authorized prior consent. Consequently, access legislation and access authority for genetic materials of States would be in the making for all the CBD member countries.

Under the circumstances, a proper IPR policy thus should be in place, which should strike a good balance between the knowledge-driven technology products for the country and the industrial development issues, realising that both of them could not be independent to each other. The IPRs are the lifeline of the R&D based knowledge-based technology industry and they encompass the right of corporate houses to have a chance of recovering their investment and have a return on capital sufficient to safeguard the interest of the stakeholders. In the emerging technologies the competitive edge will be a key driver for doing and enhancing business, whereas the competitiveness is dependent on developing new and advanced technologies. Thus, the technological innovations are facilitated by the IPRs. In a nutshell, the innovation will be the main anchor for developing competitive edge in the business with emerging technologies.

The current market size of biotechnology products is reported to be approximately US $ 1.5 billion and is expected to grow to US $ 2.5 billion by the year 2005. This estimate, however, includes hybrid seeds, tissue culture plants, fermentation derived products including antibiotics, bakers' and distillers' yeast and biological cultures. The current composition of biotech products is largely composed of therapeutics and diagnostics products for human health care, industrial enzymes and contract research services. The introduction of Bt cotton would provide fillip for the agri-biotech products further. Thus, in order to see the opportunities it is important to take cognisance of a number of global trends, viz. 70 per cent of the products under clinical testing are rDNA products or gene based products emanating from small and medium size companies; approximately 25 per cent of R&D is outsourced by drug majors. The baseline revenues of CROs in 2000 were estimated at US $ 7 billion and are growing at 30 per cent per annum. Outsourced R&D is estimated to account for 40 per cent of R&D expenditure by the year 2008. Approximately 20 per cent of the drug revenues are paid out by the drug majors as royalties on licensed products and technologies. The R&D expenditure of the top 20 pharma majors has more than doubled over the years, i.e. from US $ 20 billion in 1995 to US $ 40 billion in 2000 and it is expected to increase exponentially to more than US $ 100 billion by the year 2010. The genomics, proteomics and other informatics-based research is expected to result in an exposition in the number of these for drug discovery which will expand both opportunities and challenges for new drugs. This would dictate the focus of research to disease subsets and differentiate treatments. The big pharma majors will be forced to cut R&D expenditure and speed up R&D programmes through collaborations and contractual R&D initiatives with smaller biotech companies and CROs. There is an urgent need to reduce drug development cost through reduction in the cost of clinical trials where countries like India and China are in a strong position to provide low cost clinical trials. With all these global factors the opportunities for the biotech business are vast which require a stronger IPR system. Apart from developed countries, the developing countries also find applications of biotechnology in diverse areas as follows:

Health care. Biotechnology can be used to arrive at novel and innovative approaches to meet the needs of society providing better immunogens, diagnostics and tools, etc., and healthcare management for ageing populations and poor countries.

Crop production. Biotechnology can deliver improved food quality and environmental benefits through agronomically and nutritionally improved crops. It may be used to produce foods with enhanced qualities like desired nutritional benefits.

Non-food uses of crops. Biotechnology can also improve non-food uses of crops as sources of industrial feedstock or new materials such as biodegradable plastics. For example, canola is now being used to produce high-value industrial oil. Under the appropriate economic and fiscal conditions, biomass can contribute to alternative energy with both liquid and solid biofuels (e.g., biodiesel and bioethanol) and processes such as bio-desulphurisation. It can provide tools for mass propagation of tree and woody species for fuel, fodder, afforestation and shelter in developing countries.

Environmental uses. New ways of protecting and improving the environment are possible with biotechnology, including bioremediation of polluted air, soil, water and waste, as well as the development of cleaner industrial products and processes like biocatalysis. GMOs can also be used in biomining, or the inexpensive extraction of precious metals from low-grade ores using microbes. Plants are also now being developed to mine precious metals (e.g., *Brassica*, which is being developed to concentrate gold from the soil in their leaves).

IPR Issues for Indian Sub-Continent

Traditionally, India is a country, which has the philosophy of making knowledge a public property.[2] This philosophy has done well to the country in general and to society in particular, in the long run by enabling access to such creations and knowledge to all without discrimination. Even in the recent times, when the whole of industrialized countries were busy in the protection and privatization of inventions in the area of living objects/substances such as the protection of plant varieties, patenting of microorganisms and animals, such steps were generally not accepted by the developing countries including India. However, this philosophy and situations did not prevent industrial growth and prosperity in developing countries, despite the fact that they were slow for various reasons.[3] The advancement in the technological capabilities resulting in increased industrialization and with changes in international situations many countries came together and transformed GATT to WTO to include their commitments to the IPR as contained in the Agreements of WTO. Though WTO is a rule-based organisation, it encourages TRIPs plus protection of knowledge. The traditional Indian philosophy and practice in society has thus been opposite to this extreme privatisation of knowledge. Therefore, consistent with Indian culture, efforts have been made to create more room from within the provisions of the WTO to enable India to keep inventions in modern biology and biotechnology more in the public domain.

Thus, realising the potential of biotechnology and its relevance to the needs of society, the Department of Biotechnology, under the Ministry of Science and Technology, which is the nodal ministry for all policy issues, has always emphasised on the development of all facets of IPR in biotechnology. The protection of inventions through patenting or through other suitable methods has been given importance for innovations and industrial development. The Department has been instrumental in bringing together academia, industry and research institutions to work coherently for a strong IPR system in the country. Since India has been practicing conventional biotechnology for a very long time, there are many issues pertaining to unprotectable intellectual property. All inventions cannot be, or rather, should not be, protected due to various reasons because of various strategic considerations involving moral and ethical issues, e.g. inventions related to country's defence, inventions related to human and animal body, etc. However, such unprotected intellectual property would vary from country to country and a standard thumb rule cannot be framed for the same because of various degrees of distinctions between discoveries and inventions.

Generally speaking, most of the countries exclude from patenting, the discovery of scientific theories and laws, methods of performing mental acts, discovery of natural products and processes, production of new substances with the use of biological processes, aesthetic creations, naturally occurring living substances, etc. During the last two decades or so, some countries have included patenting of many of the earlier unpatentable inventions such as microorganisms, animals and plants. The scope of ethics and morale has also been narrowed down considerably in due course of time. However, there is no uniformity in all countries, although micro-organisms are currently patentable in many countries, plant varieties are patentable or protectable under *sui generis* systems and animals are also patentable in some countries. The patentable materials for many biotech inventions are the genetic resources, which had been freely available to countries before the introduction of the Convention on Biodiversity (CBD). In the past, many such materials had freely moved across the countries. The possession by countries of such materials is neither illegal nor can laws be enacted to bring them retrospectively under the principles of sovereignty. The patenting of life forms have always been a point of concern on which the industrially developed nations thrived upon. Various milestones in patenting life in the IPR regime can be seen in Table 1.

In Indian context, the intellectual property rights including patents are granted under the sovereign prerogative of the country according to the patent law like in other countries, i.e., they are effective only in the country. *Prima facie* the patents are only granted to a process or a product (as on date, only Exclusive Marketing Rights (EMR) for qualifying products), which meets the criteria of patentability. As and

Table 1: Patenting Life: Milestones in Biotech Patent Protection

1873	-	Pasteur got US Pat no 141.072 - "Yeast an article of manufacture"
1969	-	Animal Breeding Methods - German Federal Supreme Court accepts
1975	-	Microorganisms are patentable - German Federal Court
1980	-	Microorganisms become patentable in USA (*Diamond vs. Chakrabarty*)
1985	-	Plants/tissues/ tissue culture, Seeds become patentable: US PTO
1987	-	Multicellular Organisms are patentable - US PTO
1988	-	European Patent Office grants first patent on plant
	-	US PTO issues patent on "oncomouse"
1995	-	DNA not life but chemical and patentable - EPO declaration
1998	-	Incyte Pharmaceuticals gets first patent covering ESTs
2001	-	Patent filed for 4000 human genes and proteins and codes for them by Oxford GlycoSciences
2002-03	-	The story and controversy goes on

when the information is received about patents being granted on certain non-patentable items which affect the Indian interests, the steps are taken to assess whether the grant of such patents can be challenged under the patent laws of the country concerned. As we know, there are seven areas of IPR under Agreement on Trade related Aspects of Intellectual Property (TRIPs) of WTO, viz. trademarks, trade secrets, industrial designs, copyrights, integrated circuits, geographical indications and patents. In the first six areas, Indian laws, rules and regulations, administrative procedures and judicial systems are consistent and are at par with the rest of the world. The norms of enforcement and protection proposed in the WTO are in conformity with the Indian system. However, in issues related to patents, Indian laws have been substantially different from the provisions of the WTO which have been brought in line with TRIPs with the introduction of three amendments to the Indian Patent Act 1970. The third amendment has just been made to bring in product patent to make it fully TRIPs compliant. If we look into the provisions of the WTO from the Indian Patents System (Indian Patents Act 1970), we see that they have been different in various ways as follows:

(a) WTO provides product patents in all branches of technology while the Indian Patents System provides only process patents and does not provide product patents in drugs, foods and chemicals, as on date.

(b) WTO would grant patents for any new inventions with inventive step (non obvious), capable of industrial applications (useful), whether products or processes, in all fields of technology but provide flexibility for exclusion from patentability in areas, like: (i) plants; (ii) animals; (iii) diagnostic, therapeutic and surgical methods for the treatment of humans and animals; and (iv) biological processes for the production of plants or animals. WTO, however, provides patents on microorganisms, and microbiological processes. In contrast, Indian patent laws do not allow patenting of any life form; however, patents based on microbial processes are permitted, as on date.

(c) WTO provides coverage of patent-life for all patents for a uniform period of 20 years duration while Indian system has brought it at par with WTO only recently, for processes only (including drugs, food and chemicals, which was only 7 years).

(d) WTO requires protection of plant varieties either by patents or by an effective *"sui generis"* system or by any combination thereof, while at present there is no system for protection of plant varieties in India, despite the Plant Variety Protection (PVP) Act in place.

(e) The burden of proof in case of infringement in WTO is substantially on the alleged individual who infringes a patent, while in Indian system it is on the plaintiff.

(f) WTO does not permit discrimination between imported and domestic products while according to the Indian law, importation does not amount to working of the patent.

(g) WTO requires providing same advantage, favour, privilege or immunity granted by "a Member country" to the nationals of "any other Member country".

The IPR issues before India and the developing countries include the stand that has to be taken on the distinctions between discoveries and inventions in biological area, the definitions and the scope of patentable micro-organisms, the scope of patentability or protection of other living materials like the plants and the animals, the conditions of depositions connected with the patentable inventions involving living entities including viruses, bacteria, fungi, plasmids, genes, polynucleotide sequences with useful properties, plasmids, cosmids, vectors, gene cassettes, etc. In many of these issues, the stand of the WTO is also not clear; WTO has not made any definite recommendations in most of these facets, and the subject matter is left to speculations and conjectures to the member countries. However, the IPR issues related to modern biotechnology have been raised in a number of international forums of WTO, apart from the following:

- Convention on Biological Diversity (CBD)
- Food and Agriculture Organization (FAO)
- Organization for Economic Cooperation and Development (OECD)
- World Health Organization (WHO)
- World Intellectual Property Organization (WIPO)
- Asia Pacific Economic Cooperation (APEC)
- Office of International Epizootics (OIE)
- International Plant Protection Convention (IPPC)
- Codex Alimentarius Commission (CAC)
- World Bank

There are also a number of international agreements that relate to modern biotechnology addressing the IPR issues. The most important among these are the Cartagena Protocol on Biosafety to the United

Nations Convention on Biological Diversity and FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) apart from WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

The Pharmaceutical Industry

The pharmaceutical industry has been recently in flux for allegedly placing the sanctity of patents above that of life. At such a time it is important to see that role of industry is for drug discovery and development and the IPR on medicines is the foundation on which the drug research is based. Vaccines and immunobiologicals and pharmaceutical products make a vital contribution to healthcare system. The modern drugs have contributed to increased life expectancy. The key role for the pharmaceutical industry is to discover, develop, produce and market innovative products. In view of the substantial investment and time involved to bring a drug to the market, the companies seek adequate returns on their investment. Intellectual properties are the lifeline of the research based pharmaceutical industry. They enshrine the right of companies to have a chance of recovering their investment and to have a return of capital sufficient to ensure shareholders interest. The period of market exclusivity provided by effective patent protection system is essential for the companies to sustain the vast and risky research and development investment necessary to provide new drugs and medicines and other profile actives without the patent system. Without the effective system the majority of medicines would practically perish.

Patents have attracted much of the attention for gap between rich and poor countries in access to medicine. This has exaggerated the issue of patents in developing countries, resulting in as much as 95 per cent of the WHO listed essential drugs being available off-patent. These represent a wide range of drugs to respond to most common diseases in developing countries. However, specialised drugs like that for HIV/AIDS, drug resistant tuberculosis, etc. are not accessible to the poor people. Here the ethical and moral issues in the patent system play more important role where the patent system should be applied for more societal benefits. A particular economic incentive to substantiate corporate involvement in modern biotechnology has been the granting of the patents for recombinant organisms and engineered cell lines. With the advent of rDNA technology there has been a major reinterpretation of patenting laws all over the world, so that these days living organisms and their parts and processes, including the cells and genes of humans can be patented.

Biodiversity

The race for discovering new lead molecules has become very prominent in the drugs and pharmaceutical sector. Plant, microbial and animal biodiversities are all being mined by high throughput screening techniques for New Chemical Entities (NCEs). For example, the Himalayan yew tree has given a million dollars cancer drug, taxol. Taxol and taxol derivatives are now being mined from fungal and bacterial diversities in many parts of the world. Similarly, plant cell culture has also been successfully used to produce taxol. India's treasure in Ayurveda and Unani Medicine, which offer unique mining opportunities, further avenues for patenting of substances having larger societal importance. In accordance with the provisions of the CBD, the sovereign States have rights over their natural resources and they have the authority to determine access to their genomic resources. The CBD contains conditions for access to genetic diversity as well as transfer of technology pertaining to the biodiversity. The accesses to sharing of biodiversity are subject to prior informed consent within the national legislation and negotiations depending upon the benefits to be accrued to the donor nations. Under CBD every sovereign country needs to identify an official body that has the authority to grant access to its genetic resources and the body has to devise a mechanism for providing consent. Such mechanism should be compatible in the interacting countries so that the recipient country and the provider country can come close for the benefit of development of technologies by using natural genetic biodiversity rich in its natural form and which is not patentable through the provisions of IPR. Thus, the natural resources biodiversity is not protectable as an IPR of individuals by its mere possession under the IPR provisions of any country.

Naturally Occurring Substances

The products isolated from nature are considered as discoveries. The naturally occurring substances like proteins, glycoproteins, carbohydrates, lipids, polynucleotides, genes, DNAs and RNAs could thus be kept out of patenting which is in conformity with the provisions of TRIPs. There could be arguments in this context about how countries would look at the discovery of natural substances or apply complex steps to purify them in a manner that does not exist in nature. Therefore, the patenting of such substances would vary from country to country.

The Government Policies in Patenting

The Ministry of Science and Technology has issued the guidelines "Instructions for Technology Transfer and Intellectual Property Rights", which would help in enhancing the motivation of scientists, research institutions and universities in various research and developent projects funded by various departments of the Ministry of Science and Technology. The salient feathres of these guidelines are as follows:

a) **Ownership of Intellectual Property:** The institution shall be encouraged to seek protection of IPR rights in respect of the results of R&D. They may retain the ownership of such IPRs. Institutions would mean any technical, scientific or academic establishment where the research is carried through funding by Central/State Governments.

b) **Transfer of Technology:** The institutions would take necessary steps to commercially exploit patents on exclusive or non-exclusive basis.

c) **Royalty to inventors:** The owner institutions are permitted to retain the benefits and earnings generated out of the IPR. The institution may determine the share of inventors and other associated persons from such earnings. However, such shares shall be limited to one third of the actual earnings.

d) **Norms for the private industry:** IPR generated through joint research by institution(s) and industrial concern(s) through joint research efforts can be owned jointly by them on mutually agreed terms through a written agreement. The institution and industrial concern may transfer the technology to a third party for commercialisation on exclusive or non-exclusive basis. The third party, exclusively licensed to market the innovations in India, must manufacture the product in India. The joint owners may share the benefits and earnings arising out of commercial exploitation of the IPR. The institution may determine the share of the inventor(s) and other persons from such actual earnings. Such share(s) shall not exceed one third of the actual earnings.

e) **Patent Facilitating Fund:** The owner institution(s) shall set apart no less than 25 per cent of the revenues generated from IPR to

- create a patent facilitating fund. The fund shall be utilised by the owner for updating the invention(s), filing new patents and protecting the IPR against infringement and for building competency in the area of IPR and related issues.

f) **Information:** The institution(s) shall submit information relating to the details of the patents obtained, the benefit and earnings arising out of the IPR and the turn over of the products periodically to the Department/Ministry, which has provided the funds.

g) **March in rights:** The government shall have a royalty-free licence for the use of IPR for the purposes of the Government of India.

The Challenges for Policy Options in View of International Developments

It is a well-known fact that under the intense pressure from the US and Europe, the developing countries very reluctantly accepted to include TRIPs as part of the Agreement in Marrakesh in 1994. The most controversial aspect was the provision about patents on life forms in Article 27.3 (b) which were only agreed on the condition that they would be reviewed before they come into force in developing countries in the year 2000. The review of the TRIPs Agreement was slow in starting and has been languishing for years with a clear North-South divide producing interesting discussions but no progress. At the beginning of the review, the patenting of all living matter was the major issue and it was opined that it should be banned world over under TRIPs and any regime for plant varieties should protect the rights of farmers and local communities. Another move came from the US which proposed that no kind of inventions at all should be excluded from patenting including plants and animals, which resulted into a stalemate on the review process. In the last round of Cancun Summit, it seems that some strong efforts were made to try to get something achieved through negotiations especially on the origin of the genetic material. However, the developed countries are neither willing to make it a mandatory requirement nor to link it with benefit sharing on the issue of origin of the genetic material. A number of developing countries on the other hand are demanding for strong disclosure of origin mechanism of the biological material which would not only require detailed information about the genetic material or the knowledge but also positive proof of benefit sharing and of prior informed consent.

i) The TRIPs Review: After more than four years of stalemate between the developed and developing countries, there are signs of movement on the TRIPs Review. The discussions at WTO came out with two points, viz., one about whether patent applicants have to disclose and make public the source of the genetic material or lead on inventions involving traditional knowledge, the other point being whether and how the patent system recognises traditional knowledge in its own right. The Africa Group at WTO has added a new dimension to the debate by tabling a proposal to put traditional knowledge formally under TRIPs Rules. The policy makers in developing countries resisted TRIPs from the very outset because they saw it as a threat to sustainable development on their own terms. In fact this is correct and has now been increasingly supported by critical assessment from various UN bodies and other independent analysts as well as by growing public opinion both in North and South. Several major studies and analyses have been produced by agencies such as UK-IPR Commission, UK Royal Society, UNDP and the Human Genome Organisation which call for changes in Intellectual Property Law or limitations on its use to stop its ill effects on research, innovations and developments. It has been a wide public opinion in the developing countries that TRIPs should be amended to reduce obligations on them to adopt it in full-fledged form. It has also been opined that, at a minimum, biodiversity and traditional knowledge should be excluded from TRIPs.

ii) The "TRIPs-Plus": The European Union is aggressively forcing developing countries to adopt the strictest intellectual property rules that are possible. Since 1995 the bilateral trade agreements through which the EU seeks commitments to TRIPs-Plus standards for intellectual property on life in developing countries include Sri Lanka, Palestine Authority, Tunisia, Mexico, Bangladesh, South Africa, Algeria, and Morocco. It is aiming at more than 70 poor countries forming the Africa-Caribbean-Pacific (ACP Group). The TRIPs-Plus pertains specifically to EU-trade policy and propagates the rights of the Third World Farmers to save seeds and makes it mandatory that they must join UPOV within the next four years. Apart from EU, the US and other developed countries are also doing the same from the sides. Practically speaking the TRIPs-Plus Agreement as far as IPRs on life are concerned about implementing or joining either UPOV or Budapest Treaty, does not require patent protection of plant varieties and it does not even mention "biotechnological inventions". The TRIPs has no provision for the member countries about implementing or joining these Agreements/Treaties. By implementation of TRIPs-Plus, the policy makers in developing countries have to align their laws with those of the EU or other developed countries so that their IPRs and patents (which are more than 95 per cent of all patents) be honoured by developing countries in order to facilitate their own market strategies and secure revenues. The large scale practice of TRIPs-Plus by the EU to implement bilateral treaties are also part of the competition with other major trade powers, namely the US and Japan giving preferential terms of business with the partner countries. The developing countries' policy makers should have a lot to put intellectual thoughts to these phenomena promulgated by the developed countries.

iii) **Farmers' Privilege:** The IPR applied to seeds gives breeders or whosoever that claims to have discovered or developed new plant variety, an exclusive monopoly right in relation to the seed under the Patent Laws of developed countries. That monopoly right is very strong under the Law. It will generally prevent anyone from using, producing or selling the seed without the monopoly or the patent holder's permission. In the developing countries, under the typical *sui generis* plant variety protection system, there are a few exceptions to this powerful right of the developed countries. Under this system the exception is that farmers may be allowed to save, exchange, sell or reuse part of their harvest for the next sowing season. The legal ability to reuse IPR protected seed is known as "farmers' privilege". However, this is a factual misnomer. Saving seed is as natural as eating food and this is the strength of the developing countries to produce crops of their own germ plasm. Under the Plant Variety Protection (PVP) Law this becomes a privilege to the farmers of developing countries, taken as a legal exception in the face of developed world. In developed countries, the breeders are granted the rights while the farmers are allowed to do something despite the breeders' rights for which one has to pay economic or legal consequences under the developed countries' laws. Thus the farmers' privilege should not be looked as a right in itself in the face of the IPRs applied to seeds. Tightening the loophole that allows farmers to save seeds is the easiest way to give more powers to the breeders, which should be looked into by the policy makers in the developing countries. In the international scenario of IPRs, the restrictions on the farmers in PVP Law comes in several ways often combined with other IPR Laws. For example, farmers are prohibited from saving seeds of certain crops; only certain farmers with a specific farm size or income level can enjoy the privilege; farmers have to pay additional royalty to the breeder for any seed that they saved on the farm; the farmers can save seed but cannot exchange it; the farmers can save seeds and certain categories can be exchanged but cannot be sold; farmers can save, exchange and sell seeds but only without using the name of the variety. All these restrictions are to control the market and the competition among the seed companies of the developed countries. The *sui generis* system mainly prevalent in the developing countries should keep away its provisions from all these factors of the developed world. There are many chances that the farmers privilege would be used to strengthen the breeders rights at farmers' cost in the IPR regime.

iv) WIPO's Substantive Patent Law Treaty (SPLT): For the past more than three years a new international patent treaty under the one global patent system has been under negotiation at the World Intellectual Property Organization (WIPO) in Geneva. The SPLT aims to remove most of the national flexibility in the patent systems of the member countries and pave the way for a future world patent granted directly by the WIPO. This seems to be an appealing proposal especially for the multinational and transnational corporate houses of the developed countries like the US and EU, who view patents as the primary means to control the globalized economy. However, this global patent system does not seem to be a good omen for the developing countries and their citizens who would loose even the limited freedom left by the WTO TRIPs Agreement to adjust patent systems to national developmental goals. The policy makers in the developing countries should look to the global patent system very cautiously and can always keep themselves away from the system to stop the negotiation process. This would provide them free hand and utilization of their national patents for the benefit of the country.

v) The protection of 'undisclosed' information: Under Article 39.3 of the TRIPs, the issue of protection of undisclosed information has been often referred as "data exclusivity" by the transnational corporate houses. The matter practically relates to the marketing approval granted by the regulatory authorities for the new chemical entities. The issue of data exclusivity has never been mentioned in this article rather it refers to the undisclosed information given by the companies anywhere in the world at the time of applying for marketing approval. In most of the developing countries the existing laws take care of the protection of the undisclosed information while the multinationals have been pressurizing hard for the implementation of the specific period of time for imposing data exclusivity, which would eventually lead to further greening of the patent beyond twenty years. This is another TRIPs-Plus issue would have lot of impact on the availability of biogenerics for the poor people of the developing countries at a much affordable and lower cost than in the developed countries. Apart from drugs, the issue is also important for the agrochemicals and transgenic crop products. The policy makers in the developing countries have to apply their minds while framing their regulations to keep out the biogenerics in general out of the data exclusivity regime.

vi) Ethical and Moral Issues: The rDNA technology has opened up more opportunities for making decisions on aspects of nature over which we previously have no decision making powers but were accepted as destiny. This technology fundamentally puts nature to a growing extent at our disposal and edges us increasingly into a technological relationship with our own bodies with non-human nature, thereby breaking down our traditional normative points of reference. The gene technology makes people more uncomfortable to cope with the dynamics of technological change creating more anxiety and uncertainties. This has led to new demands on political and other systems with more democratic control. There are questions that cannot be settled through the regulatory mechanisms of the law but call for broad debate within society as a whole. In the present scenario of technological advancements it is often argued that patenting is ethically neutral. Perhaps this argument stems from the philosophy that patenting by the inventers on the suitability of their inventions on the basis of set criteria of novelty, inventive steps and usefulness and such criteria have nothing to do with ethical issues. There are further arguments that if the practice of an inventor is considered immoral by societies, then by an Act of Law such inventions should be banned from patenting. This is what is being practiced in every society through its government legislations to prevent from patenting the inventions, the exploitation of which is against morality. Unfortunately, as on date there is no uniform universal code of conduct that can be applicable and useful for every society in the world and which can be taken as a baseline of ethics and morality. In this context of biological inventions the situation has become more complex especially for the developing countries.

Practically speaking, the ethics can change with time and with the societal needs. Similarly, the societal morals can also change with the change in time. However, at a particular time every country has the right to set the floor limits of ethics, which can be binding for the inventors over a period of time. The TRIPs of WTO is neutral in setting any limits of ethical issues, which can be globally acceptable. Therefore, it can be said that the baseline of morality can be drawn within the purview of sovereign states in accordance with their social and cultural norms and these norms should only have territorial applications. Keeping in view the Indian philosophy, which is based generally on the welfare of human and animals, it would not be an exaggeration to state that Indian ethics may be considered as baseline for the purpose of preventing inventions from patenting. Sustainability for the activities of animal welfare, dignity of human beings and preservation of biological wealth are important for the human beings. Therefore, the inventions in areas, which do not conform or are contrary to these activities, should not be considered the areas of patentability. Subsequently, discoveries of any natural element including the elements of partial or full sequence of genes from human or animals should not be allowed for patenting. Any invention leading to cruelty to animals without much advantage to the human beings should also not be permitted for patenting. Ethically speaking, all inventions employing human germ line, human embryos, the human cloning process as well as determination of sex of human foetuses should not be allowed for patenting.

Conclusions

Under the present international developments in the IPR system the policy makers of developing countries have a number of policy options for the benefit of society for safeguarding their national policies. The institutional capacities of developing countries for policy coordination across government, policy makers and the participatory process for IPR may be one of the weakest areas, which need to be further strengthened. It has been observed that in the context of the participation in international rule making, there exists lot of diversity among developing countries where some have no permanent representation and some are often with little contribution while some are mere spectators in the WTO and the WIPO Forums, in comparison to participants from developed world who are active and influential. The policy makers of such countries should be vigilant and should enhance their learning process before it is too late. On the other hand, most developing countries face financial and human resource constraints in implementing new legislations owing to inadequate infrastructure and office procedures and they should take the help of their neighbouring countries like India.

It is important that developing countries ensure that their intellectual property legislation and procedures emphasize, to the maximum possible extent, the enforcement of IPRs through administrative action and through the existing civil justice system. They should aim to recover the full costs of upgrading and maintaining all aspects of the national intellectual property infrastructure through national IPR registration and administrative charges. Developing countries should seek to exploit the maximum possible benefits in terms of cost reduction and administrative efficiency from existing regional and international cooperation mechanisms, through various bilateral agreements in IPR especially with another developing country in the neighbourhood. Like-minded developing countries should also make concerted efforts to support high-level dialogue on new regional and international co-operation initiatives in IPR administration, training and IPR statistical data collection and management.

Developing countries should encourage policy research and analysis on intellectual property subjects in the national interest, especially pertaining to protection of plant varieties; traditional knowledge; folklore; technology transfer; etc. In order to meet the special needs of Least Developed Countries (LDCs), in developing the modern intellectual property regime and wider institutional infrastructure, there is a need for WIPO, EPO and developed countries to commit some corpus fund for technical and financial assistance. WIPO and EPO should be formally invited to join as donor agencies of the Integrated Framework alongside the World Bank, UNDP, UNCTAD, WTO, and ITC, for the purpose. It is important that WIPO makes funds available to cover the travel, accommodation and subsistence expenses of representatives from all LDC Member States to participate in all TRIPs-related capacity building projects of WTO, TRIPs Council meetings and in those meetings at WIPO which such countries are eligible to attend. It is also important that WIPO strengthen the present systems for monitoring and evaluation of its development cooperation programmes especially for the developing countries. With these efforts the LDCs and the developing countries would be able to cope with the fast developing IPR regime where it is anticipated that the developed world would maximally utilize the resources of developing countries through various Trade Agreements of WTO.

Endnotes

[1] The following online dictionaries contain further definitions of terms relevant to modern biotechnology: http://www.fao.org/DOCREP/003/X3910E/X3910E00.htm, www.hon.ch/Library/Theme/Allergy/Glosaary/allergey.html, www.sciencekomm.at/advice/dict.html.

[2] This has been reflected in the ancient Indian way of life when seers preached freely and Gurus distributed knowledge through Gurukulas; where the authors responsible for many ancient creations and knowledge have not claimed their ownership or even authorship in the benefit of society.

[3] India for example became capable to increase its food production significantly to about four times from the 1950s level through scientifically developing more productive plant cultivars including varieties and hybrids, and by adopting dwarf plants of wheat and rice in Indian agriculture system. The global milk production became the highest in India with the adoption of scientific techniques and with the improvement of milking animal varieties.

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Patenting of Biotechnological Innovations

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Introduction

'Intellectual Property Rights' (IPR) is a term incorporating a collection of rights which are granted to individuals or organizations for works that involve a creative input or the exercise of intellect. The different rights have been broadly classified into two categories, viz. Industrial Property, which have a commercial and practical value, and Artistic and Literary Property, which have a creative value.[1]

The one common characteristic of all the different kinds of IPRs is that the right granted in all these cases is a negative right, i.e. it prevents third parties from the exploitation (making, using, selling, offering for sale, importing, copying, etc.) of the work that is the subject matter of the right without a licence or authorization from the right holder. These rights are gaining importance now as their value in industry is increasing.

This paper is focused on the role of patents in the area of biotechnology, an important tool to protect biotechnological inventions. Patents are exclusive rights granted to inventions that satisfy the criteria of patentability in the form of novelty, non-obviousness and potential for industrial application.[2]

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TRIPs and Patent law

The need for a uniform law to harmonize the different laws related to the protection of intellectual property prevailing in the various countries resulted in the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement that came into force in 1995. It provides the minimum standards of patent protection that require mandatory compliance by all the member countries. In India the patent law was amended so as to bring it in compliance with the TRIPs agreement. This has led to the grant of product patents in the field of chemicals, pharmaceuticals, food and biotechnology which was not possible previously.

Article 27 of the TRIPs Agreement forms the basis of the changes in the patent law. Article 27.1 states that *"patents shall be available for all inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.... Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."*

The present age of technology arguably belongs to biotechnological innovations. Biotechnology may be defined as the application of science and engineering in the direct use of living organism or parts or products of living organisms in their natural or modified forms.[3] Biotechnology encompasses recombinant DNA technology which can be used to modify the genetic material of living cells to produce new substances or perform new functions. The innovations relating to the field of biotechnology are not limited only to the field of genetic engineering. Many of the said innovations have been used for obtaining drugs, the synthesis of which would have been chemically impossible because of the sheer complexity of the resultant molecule.

The patent protection is obtainable for most of the biological innovations. The protection thus provided serves as an incentive for further development and technical innovation.[4] Biological inventions in the patent system are similar to chemical inventions. These include such inventions as biological, micro-biological, biotechnological, genetic engineering and medical inventions. Biotechnological inventions, which may be patentable, can be broadly categorized as:

- Products in the form of chemicals, organisms, plant extracts, fermented material;

- Processes or methods for producing useful products; and
- Compositions or formulations of products such as vaccines, proteins, hormones.

The frontier areas in biotechnological inventions include DNA sequencing methods, genetically modified organisms, stem cell research, gene therapy, diagnostic kits, vaccines, bio-informatics and cloning.

The TRIPs agreement also specifies inventions which may be excluded from patentability. Article 27.2 of TRIPs states that *"Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their* law." This provision has also been incorporated into the Indian Patents Act under section 3 (b).This sub section excludes inventions, the use of which would be contrary to public order and morality or would be seriously jeopardizing animal and plant life. However, this provision is not a compulsion imposed by the TRIPs agreement for the member countries to implement.[5]

Further, Article 27.3 (b), TRIPs, states that *"Members may also exclude from patentability: plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and micro-biological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof."* This forms the basis for the provisions on the exclusions from patentability under the Indian Law. The list of exclusions includes inventions which are frivolous and are contrary to the well established physical laws of nature such as a perpetual motion machine. The Patents Act also excludes all forms of discoveries, scientific theories, mathematical methods and abstractions.[6]

The Indian Patents Act also considers the mere discovery of a new form of a known substance as non-patentable. The same kind of treatment is imparted to a new use of a known substance. Section 3(d) has been significantly amended and departs from the previous amendment in the Ordinance. The Act has included a list as an explanation to the subsection (d), which would limit the scope of patentability of any chemical. It would appear that a mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance would not be patentable. However, the yardstick to measure the degree of efficacy is still unclear.

The act also does not allow the patentability of computer programmes. The amended act restores the position of patentability of software programme as that which existed before the amendment. The position taken by India is different from that of the United Kingdom, which allows the patentability of software programmes with the stipulation that the use of the computer programme should be for the attainment of some technical effect.

The Patent Act now also allows for the opposition against the grant of patent. As per the Act, any person within three months from the date of publication can apply and oppose the grant of a patent.[7]

The Patent Act also states that the use of the patented invention, without the consent of the inventor, would be considered as an infringement if the use of the invention is for the purposes of research and development only.

A new section has been added to the Act through the Ordinance. The Amending Act has further modified the provision incorporated by the Ordinance and appears to conform to the Doha declaration.[8] The section provides for the export of patented pharmaceutical products to any country facing public health problems and having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product.

In case the importing country grants compulsory licence or notifies or allows the pharmaceutical products, the controller of patents can grant licence for the manufacture and permit the export of the concerned products. The controller, therefore, has the statutory rights to grant a licence at any time, even if the conditions for grant of licence, as specified under section 84, do not exist.

The following sections cover the issues on biotechnology pertaining to the question of patentability of micro-organisms, animal, plants and gene or DNA sequences.

Patenting of Micro-organisms

Article 27.3 (b), of the TRIPs agreement forms the basis for the provisions on the patentability of micro-organisms. Nevertheless, micro-organisms also have to satisfy the novelty, utility and non-obviousness criteria to be patentable. However, TRIPs agreement does not provide a precise definition of micro-organisms. The term micro-organism is generally understood to include viruses, bacteria, yeast and other forms of fungi, protozoa and unicellular algae and non-differentiated animal or plant cells (cell lines, stem cells and *calli* in plant tissue-culture). Even though micro-organisms can be patented as per TRIPs Agreement; one is often faced with a dilemma whether at all micro-organism constitute a patentable subject matter since they are real "life forms".

The law which opened the gates for inventions in the field of biotechnology, particularly micro-organisms, was by a landmark judgement of the US Supreme Court in 1980 in *Diamond v. Chakraborty*.[9] The dispute was with regard to a modified micro-organism developed by Ananda Chakraborty which had the ability of breaking down crude oil. This property was introduced into naturally occurring bacterium to produce a genetically modified organism. The Commissioner of Patents in the US held that the subject matter of the invention was a living organism and was, hence not patentable. The US Supreme Court Judge, however, decided in favour of the patentee and stated that everything under the sun is patentable. The test laid down by the court for the patentability of living organisms was whether the living organism is a result of human intervention and that the genetically altered micro-organism constituted patentable subject matter as either a manufacture or a composition of matter well within the definitions laid down by the US patent law.[10] The landmark judgement paved the way for the grant of a number of such biotechnology related patents.

The position of law in the United Kingdom and the European Union is similar with respect to the patentability of microorganisms. The patent law of the United Kingdom can be traced back to the 17th century with the Statute of Monopolies of 1623 being the base on which the modern patent law of the country has evolved. The Statute requires the invention to fulfill the condition of being a *manner of new manufacture*[11] for it to qualify as a patentable subject matter. This definition was carried forward to the UK Patent Act of 1949 together with the criteria for novelty for determining whether the subject can be considered to be a valid subject matter.

The Patents Act of 1977 was a revolution over the old patent act. The new act was meant for giving effect to the provisions of the Patent Cooperation Treaty (PCT) and the European Patent Convention (EPC). The EPC formed the basic framework of the new Patent Act of 1977 and was in form a step to harmonize the patent law across Europe. Moreover, the decisions passed by the European Patent Office (EPO) are often considered by the UK courts as a precedent.

The criteria for patentability of an invention as considered by the UK Patents Act 1977 include novelty and inventive step.[12] The concept of the invention is being novel and involving an inventive step is common for all countries. The US law requires that the invention under consideration should also have a utility. The position in the United Kingdom is, however, different requiring the invention to be useful in any kind of industry, i.e. possessing an industrial application. The stipulation to this condition is that the invention should not be used as a method of treatment.[13]

The UK Patents Act further mentions that innovations involving discoveries, scientific theories, mathematical methods, literary works and presentation of information are not inventions.[14] Moreover, the Act specifies inventions for which patent shall not be granted. This includes inventions which are contrary to the public morality. The UK Act allows the patentability of microbial processes or the micro-organism per se.[15] Going by US and European precedents, it would appear that only such micro-organisms that are a result of human intervention would be patentable. Naturally occurring micro-organisms are likely to be excluded from patentability, unless the micro-organism loses its natural characteristics as a result of human intervention. However, subsequent to the human intervention, the involved micro-organism should satisfy the criteria of possessing an industrial applicability, i.e. the organism should not be devoid of a utility.

The Act also requires that the sample of the micro-organism which forms the subject matter of the claimed invention be deposited not later than the date of filing of the application. The deposit of the sample of the biological material is required to ensure that the specification is sufficiently enabled so as to render it workable.

In India, the position of patentability of microorganism is parallel to that of the UK and Europe.[16] The Calcutta High Court gave a path breaking judgment in the case of *Dimminaco A.G. v. Controller of Patents & Designs*[17] which has been hailed as the Indian counterpart to *Diamond* v. *Chakraborty* of USA. The case related to the patentability of a process for preparation of Bursitis vaccine useful for protecting poultry against infectious bursitis. The ground for rejection of the patent by the Controller was that the Examiner found that the 'claim' did not fall within section 2 (1) (j)[18] of the Patent Act, 1970 and, therefore, is not an invention.

The case is important because it addressed a gray area in the law with regard to what constituted patentable subject matter. The main point of contention between the parties was whether the phrase 'method of manufacture' used in section 2 (1) (j) could be said to include a living organism. The issue was whether process patents would be allowed in cases where a living micro-organism formed a part of the 'substance' being manufactured. The appellants contended that the claim was only for the process of preparation of the vaccine and not for the product (vaccine) itself. Such a process being new should have been granted a patent.

The court held that *"merely because the end product of a process contains a living organism does not preclude the process from being an invention and consequently patentable."*[19] Further, the court found that the patent claimed was useful as it protected poultry against contagious disease and the end product resulted in a new article. Since the above criteria were satisfied the court affirmed that the process leading to the 'manufacture' of the end product would be an invention. The court identified the 'vendibility'[20] test as the most effective test to determine whether the process of manufacture ought to be patented or not. A vendible product is one that can be commercially transacted. The opinion of the court was that the vendibility test was satisfied in this case as the invention resulted in the production of a vendible item. What is evident from the judgment is the forward-looking attitude of the judiciary. The traditional belief in India has always been that any process involving living organisms are not patentable.

Microbiological processes are patentable subject matter after the implementation of the Second Amendment in May, 2003. Earlier, the deposits of the culture samples were required to be made at an institution authorized by the Government. After the third Amendment, the deposit is now to be made as per the Budapest Treaty to/at an International Depository Authority. The deposit of the culture sample in India can be made at the Microbial Type Culture Collection (MTCC) and Gene Bank at the Institute of Microbial Technology at Chandigarh. The Act also provides other conditions to be fulfilled at the time of deposit of the sample as follows:[21]

- all characteristics for identification of the microbial sample
- access to material allowed after publication of the application
- disclosing the geographical source of the biological material

From above it can be gathered that even though in the absence of a working definition, various countries are allowing the patenting of micro-organisms. However, there are debates regarding the patentability of micro-organisms in many countries. Some countries consider that there are disadvantages,. hence it is imperative to clearly differentiate the microbes claimed from the naturally occurring microbes and show that the biological material is an outcome of invention and not a mere discovery. Clearly, the recombinant, mutated and adapted microorganisms are patentable as these are not naturally occurring organisms. Therefore, the position that India adopts regarding the patentable matter will become clear since the Act has been amended recently to include product patents for microbes.

Patentabilty of Animals and Plants

The TRIPs agreement provides that the Member States may exclude plants and animals from patentability.[22] This option has been adopted by a number of countries such as the United Kingdom, Europe and India. The issue of the patentability of animals arises mainly because the patentability of animals is considered to be a moral issue rather than a legal one.

In the US the attitude of the USPTO after the landmark judgment of *Diamond v. Chakraborty* is very tolerant towards the grant of patents for animals and living subject matter.

The UK Patent Law and the EPC does not permit the grant of patents for animal and plant varieties as stated in Article 4 of the Biotechnology Directive (98/44/EC). However, Article 4.2 of the Biotechnology directive (98/44/EC) states that inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety. Further, Art 6. of the Directive (98/44/EC) states:

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to order public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
   (a) process for cloning human beings;
   (b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

This issue of patentability of the animals along with the inventions being against the morality or public order was dealt with in the Harvard Oncomouse case.[23] The invention related to Oncomouse which had been granted a patent in the US. The Oncomouse or Harvard mouse was a genetically modified mouse carrying a specific gene called an activated oncogene thus making the transgenic mice harbouring the activated oncogene highly susceptible to cancer. The grant of the patent application was questioned based on public order and morality under Article 53(a). The EPO contended and accordingly held that the Oncomouse and other oncogenic animals were not contrary to Section 53(a) of the EPC which is similar to Section 1(3)(b) of the Patents Act of 1977(UK). It was also explicitly stated that other cases would be viewed differently in accordance with Section 53(b) of the EPC and the final outcome would be on a case to case basis.[24] In the recent decision of the Oncomouse[25] case the previous opinion was upheld restating that the transgenic animal is patentable but denied the patent to the other rodent species. In principle, transgenic plants and animals are patentable in Europe based on the EC directives (98/44/EC). However, plant and animal varieties are not patentable subject matter in Europe. The position of India with regard to the patenting of animals is different from the UK Act. India denies patents to animals as whole or part thereof thereby clearing all doubts relating to the patentability of animals or transgenic animals.[26] The Indian Patent Act also bars plants and plant varieties from patentability. This is in compliance with the TRIPs agreement as it requires that the plant varieties should be offered protection either through a patent system or a *sui generis* system or a combination of both. The exclusion of plant varieties from the patent protection arises because of the existence of plant variety protection laws in various countries. This came as a result of observance of the contracting parties to the 1964 International Convention for the Protection of New Varieties of Plants (UPOV Convention). The removal of the protection of plant varieties was a step to counter the dual protection offered by the patent law and the PVP. The US is the only country which allows dual protection for plants and plant varieties.

In UK and EPO a question which arose from the reading of the provisions is that whether genetically modified plants are patentable subject matter or not, as the provisions given in the law only exclude plant varieties from patentability. This was clarified in the case of *PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors*[27] which also laid down a comprehensive definition of what constitutes a plant variety. The basic characteristics which defined a plant variety included the following:

- Plant grouping within a single botanical taxon of the lowest rank,
- Possesses at least one single transmissible distinguishing characteristic, and
- Sufficiently homogeneous and stable in it's distinguishing characteristics.

The Technical Board also stated that plant cells which are genetically modified are not plant varieties and thus patentable. The Technical Board further considered what constitutes an *essentially biological process* for the production of plants. It held that a process would not qualify as an essentially biological process if the process for the production of plants should comprise at least one technical step which could not be carried out without human intervention and that step should be decisive so as to give the final result, was within the parameters of patentability.[28]

In India, the plant varieties may be protected under Protection of Plant Varieties and Farmers' Rights Act (PPVFRA). This act will come into force soon for protection of plant variety as it is a requirement under the TRIPs agreement.

Patenting of Genes and DNA Sequences

Another aspect which is important to consider under biotechnology is patentability of genes and DNA sequences. Genetic inventions encompass medical, agricultural, environmental and industrial applications. Patenting of genes would be essential since it would provide an incentive for the manufacture of new and improved therapeutic drugs and its application in different areas of biotechnology.

The DNA molecule is a linear polymer in the form of a double-stranded, double-helix structure. The recombinant technology involves a number of techniques for cutting, splicing and ligating together different pieces of DNA. When segments of foreign DNA are transferred into another cell or organism, the substance for which they code may be produced along with substances coded for by the native genetic material of the cell or organism. Thus, these cells become "factories" for the production of the protein coded for by the inserted DNA.[29] The resultant product may be one whose structure is already known or a molecule which has been isolated in a pure state or even a product known by its activity in an impure mixture.

At present, patents for gene or DNA sequences mostly include methods of isolating the genes or DNA sequences and use of the genes for expressing DNA to produce a particular protein, which has utility. However, it is now being questioned whether the genes (product *per se*) themselves are a patentable subject matter. The issues that have been put forward with regard to the patentability of genes include the following:

- Genes are naturally occurring and not new.
- Genes are basically discoveries, i.e. the invention claimed is actually a disclosure of something already in existence or have they essentially added something to the wealth of human knowledge.
- The process involves gene isolation and cloning which are well known processes and hence no inventive step is evident in the claimed invention.

The USPTO and EPO have addressed these issues and stated that product patents for genetic inventions are allowed provided that they meet the requirements of patentability. In the US, the issue regarding the patentability of genes was dealt with in *Amgen Inc v. Chugai Pharmaceuticals*.[30] In this case the invention was regarding erythropoietin (EPO). The claim was not for a gene itself, which would be within the scope of the natural gene, but for a vector and a genetically modified cell which contained the gene sequences. The invention, therefore, met with the requirements of novelty as genetically modified cells and vectors are not naturally occurring. The claims to the protein produced as a result of the invention were related to a protein in a modified or pure form. Moreover, the inventors had only a small part of the sequence information before isolating the full length gene from a human complementary DNA (cDNA) library which codes for the EPO protein and their invention required a lot of human ingenuity which constituted their inventive step.

In this case, it was contended that the claimed invention is not the DNA sequence encoding the human protein since the gene sequence is a non-patentable natural phenomena free to humankind and reserved exclusively for none. The claim that was for an "isolated gene" constitutes a patentable subject matter.

In addition to gene sequences being patented, a number of ESTs were being applied for protection in the US. In such inventions, the utility of ESTs were not clearly defined and raised a lot of debate regarding the patentability and the issues regarding the utility of the DNA sequences. The USPTO in 1999 published new utility guidelines for genes and DNA sequences which involve a three step test for utility as follows:

1. Does the invention possess specific utility? This implies that specific use of the gene should be apparent.
2. Does the invention possess a substantial utility? This implies that the invention in question should define a 'real world' use. Utilities that require further research to ascertain the utility are not substantial.
3. Does the invention possess credible utility? A credible utility is assessed from the workability standpoint of the invention as seen through the eyes of a person ordinarily skilled in the art. Claims to invention which are frivolous are not considered to possess credible utility.

Earlier, the United States Patent Office was of the view that gene coding for a protein of a known sequence was obvious and was hence not patentable. However, the Court of Appeals for the Federal Circuit ruled that if one bears in mind the fact that only a miniscule part of the genetic code is responsible for the production of the relevant protein, and then in that circumstance, the process of choosing a particular sequence among many is an inventive step of the invention.

Similarly, the EPO released a Directive in 1998 to clarify matters related to patentability of biotechnological inventions. The Article 5 of the EC directive (98/44/EC) states the following:

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

In summary, DNA sequences are patentable subject matter as these are considered as synthetic molecules isolated from the organisms and characterized and produced as recombinant molecules containing the information as in the natural genes. However, the criteria of novelty, inventive step and industrial application must be satisfied for patent Tissue Plasminogen Activator (*tPA*) ability.

The question of patentability of DNA sequences and issues related to public order and morality were also brought forth in the *HOWARD FLOREY/Relaxin* case.[31] In this case the invention was regarding the production of a human protein called relaxin. The protein was obtained from a cDNA fragment derived from human samples. It was claimed by the plaintiffs that the invention exploited a medical condition of the human body and that such use of cDNA fragment was considered unethical. The Opposition Board held that the isolation of an mRNA for deriving the corresponding cDNA encoding a human protein was not immoral and neither is the patenting of a DNA fragment unethical.

Again, as mentioned in the earlier part, the question of the inventiveness of an invention involving genes has to be answered. This arises when an inventor merely uses the already known common procedures to isolate the obviously desired protein. The fact that the technology involves fast and revolutionary innovation in the field makes it difficult to decide what would have been the state of the prior art at the relevant filing date. A similar situation was brought up in the case of *Genentech v. Wellcome* in the Court of Appeals.[32] In this case Genentech's patent claimed a DNA process for the production of a *tPA* protein. The appeal by the patentees for the grant of the patent was rejected by the Court of Appeals on the basis that the main claim which was for a substance was already a part of the state of the art. Moreover, it was stated that the product was ***obviously desirable*** to produce by recombinant DNA technology, that the methods employed for the purpose of obtaining the product were standard ones and that the invention thus lacked an inventive step.

Another aspect which has to be considered for patentability of biotechnology inventions is the sufficiency of the specifications. In many cases the inventions are unable to describe the inventions sufficiently well so as to achieve the results as claimed by it. The effect of making a broad claim has frequently led to the invalidating the patent for lack of subject matter. However, in the case of biotechnological inventions a new scenario arises where a given result may be obtained by different means and the various means themselves have nothing in them which can relate to the subject matter disclosed in a specification. This is a type of insufficiency which is called the *Biogen Insufficiency*. The term was coined in the House of Lords decision in *Biogen v Medeva*.[33] The patent claimed a recombinant DNA molecule characterized by the sequence of the antigen. The patent specification covered both the types of antigens, viz. core and surface antigens. The patent was held invalid in the House of Lords which consented that even though the patent enabled the production of both antigens by the single method described, the claims were for every way of achieving the stated result, viz. the production of antigens.

A number of patents have been granted in many countries which deal with genetic inventions. These generally cover claims[34] and have been compiled by Ulrich Schatz of the EPO.

- Genes or partial DNA sequences such as cDNAs, ESTs, SNPs.
- Regulatory elements such as promoters, enhancers and silencers.
- Proteins encoded by these genes and their functions in the organism.
- Vectors used for the transfer of genes from one organism to another.
- Genetically modified micro-organisms, cells, plants and animals.
- Processes used for the making of a genetically modified product.
- Uses of genetic sequences or proteins which include: genetic tests for specific genetic diseases or predisposition to such diseases; drugs developed on the basis of the knowledge of proteins and their biological activity; industrial applications of protein functions.

There are at least three categories of gene patents in the medical field.

I. DNA coding for useful polypeptides/proteins

DNA sequences code for a number of therapeutics polypeptides of proteins. These DNA sequences can be used for commercial production of useful proteins in the medical field and thus deserve protection provided these innovations meet the standard criteria of patentability. Similarly, DNA sequences may code for useful proteins in the area of microbial biotechnology and plant biotechnology. There are many applications in the microbial biotechnology where genes have been introduced into microbes to produce recombinant micro-organisms. These recombinant micro-organisms can produce enzymes or can have application in bio-remediation such as clean up of effluents from industries or clean up of oil spills.

II. DNA as diagnostic tools

A number of diagnostic methods involve the use of genes or DNA sequences to differentiate between the normal or abnormal alleles in humans. The normal allele confirms a healthy condition whereas the abnormal alleles may be responsible for the diseased state. The genes/ DNA sequences may be responsible for the diseases when they mutate and express the wrong product or are deleted and do not express the product. Patents have been granted for such inventions both in US and Europe. The classical example is the US Patent on breast cancer genes (BRCA1 and BRCA2) and their use in diagnostic testing. The claims in such patents generally cover the following:[35]

(a) The wild type gene and or mutated forms of the wild type gene,
(b) The primers for amplification of the above DNA sequences,
(c) Methods for deduction of wild type or mutated gene/DNA sequences, and
(d) Kits for the diagnostic testing.

The patents generally do not code for the target products.

III. Genes which control pathway-gene therapy

A number of innovations are based on the receptors and or genes involved in biological pathway or are useful for gene therapy.[36] When such gene is located, it may be possible to correlate a malfunction in the pathway with a mutation or loss of this gene. The cDNA and the encoded polypeptide would be considered targets for diagnosis and drug discovery.

From the above discussions, it is evident that as compared to the US the patent law of the United Kingdom and Europe are conservative when it comes to granting patents regarding biotechnological inventions. This basically stems from the fact that the United Kingdom along with Europe preferably would want to stick to the notion of not wanting to grant patents which would invoke mixed reactions from various sections of the community. The same standpoint is taken by India which also shares the same feeling. The Indian Patent Law too disallows the patenting of living subject matter but draws an exception for the patentability of micro-organisms. This also implies that the Indian Patent Law is also open to the patenting of genetic material and their products too, provided they fulfill the criteria of patentability. However, the position of the Indian Law differs from the UK Law in the respect that India does not allow the patenting of animals as whole, too. Accordingly, inventions relating to transgenic animals will not be allowed protection in India.[37]

It is quite apparent that the field of biotechnology is ever growing and that what we see now is perhaps only the tip of the iceberg. However, with the increasing innovations in the field it has become quite essential that adequate amount of protection is made available but at the same time respecting the constraints of the modern society.

Endnotes

[1] Integrating Intellectual Property Rights and Development Policy, CIPR (September, 2002).

[2] Art. 27.1, TRIPS Agreement.

[3] Sec 3(1) Canada Environmental Protection Act.

[4] Article 7 TRIPS Agreement.

[5] Article 27.2 TRIPS Agreement.

[6] Sec. 3, 1970 Patents Act, India.

[7] Sec. 25, 1970 Patents Act, India.

[8] Sec 92A, 1970 Patents Act, India.

[9] *Diamond v. Chakraborty* 447 US 303.

[10] 35 USC. 101 Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

[11] Sec.6 of Statute of Monopolies, 1623.

[12] Sec. 1 of UK Patents Act, 1977.

[13] Sec. 4(2) Patents Acts, 1977.

[14] Sec. 1(2) Patents Acts, 1977.

[15] Sec. 1(3)(b) Patents Acts, 1977.

[16] Sec 3(j) of the Indian Patents Act, 1970.

[17] AID 1of 2001.

[18] Section 2 (1) (j) states that "invention means any new and useful: art, process, method or manner of manufacture; machine, apparatus or any article; substance produced by manufacture, and includes any new and useful improvement of any one of them."

[19] AID 1of 2001.

[20] In Rantzen's Application, (1947) 64 RPC 63 at 66, Evershed J. commented on the vendibility test as follows: "In the great majority of cases at any rate, the use of the phrase 'vendible products' in reference to the result of the process of manufacture aptly assists in the true interpretation of the word 'manufacture' by laying proper emphasis on the trading or industrial character of the processes which are intended to be comprehended by the Acts... the problem always remains one of the application to the facts of the particular case of the statutory phrase 'manner of manufacture'... it would not be right... to give to the term 'vendible product' a

narrow or rigid construction "See contra opinion of Lloyd-Jacob J. in Virginia Carolina Chemical Corporations Application, (1958) 75 RPC 35.

[21] Sec 10(4) (d) of the Indian Patents Act, 1970.

[22] Art. 27(3)(b) of TRIPs Agreement.

[23] HARVARD/Oncomouse EPO Decision T 0019/90.

[24] Ibid.

[25] HARVARD/Oncomouse EPO Decision T 0315/03.

[26] Ibid. at 10.

[27] PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors 1995 O.J.E.P.O. 545, [1995] E.P.O.R. 501.

[28] Ibid. Paras 29-30.

[29] cited from http://www.genomicglossaries.com/content/instrument_tech.asp

[30] 502 US 856 decided in 1991.

[31] HOWARD FLOREY/Relaxin 1995 O.J.E.P.O. 388.

[32] Genentech v. Wellcome [1989] R.P.C. 147.

[33] *Biogen v Medeva* [1997] R.P.C. 1.

[34] Genetic Inventions, Intellectual Property Rights and Licensing Practices, OECD Publications.

[35] ibid at 31.

[36] ibid.

[37] Sec 3(j) The Indian Patents Act, 1970 .

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Bt Cotton and India's Policy on IPRs

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The commercial cultivation of *Bacillus thuringiensis* (Bt) cotton in India has led to enormous debate on the benefits and costs of genetically modified crops. The promoters of Bt cotton have tried to demonstrate its yield potential and reduction in pesticide use but opponents have argued against the environmental effects and disputed claims of high yields. While the cost-benefit calculations of Bt cotton performance in India have been analysed in numerous studies, the linkage of the Bt cotton issue with India's policy on intellectual property rights (IPRs) has not been given adequate attention. The case of 'unauthorized' varieties of Bt cotton being sold without severe punishment in India has also led many to dismiss IPR as a factor in policy-making. However, such an omission would be shortsighted as IPR issues are set to figure in the agenda in the days ahead. It is a crucial period for review of India's policy on genetically modified crops with the conclusion of the initial three years period for the commercial release of Bt cotton in India. The review process must not overlook IPR issues relating to Bt cotton if India is to frame a long-term rational policy on genetically modified crops.

Bt cotton is a genetically engineered variety of cotton designed by Monsanto, a company based in the US, to reduce or eliminate the need to spray for bollworms. Monsanto created the variety by introducing the Bt gene into the cotton plant. The cotton variety so developed,

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Bollgard, produces the toxin in all parts of the plant such that major insect pests of cotton are controlled, and when bollworms feed on the Bt cotton plant, the protein stops the larva from feeding further and causes its subsequent death.[1]

Bt Cotton is the first and only transgenic crop approved initially for commercial cultivation in India in six states, namely, Andhra Pradesh, Gujarat, Karnataka, Madhya Pradesh, Maharashtra and Tamil Nadu for three Bt cotton hybrids (Bt MECH 162, Bt MECH 184, Bt MECH 12) in March 2002 for a period of three years. The government in April 2004 approved a fourth transgenic crop RCH 2 Bt developed by Rasi Seeds for commercial cultivation in central and southern parts of India.[2] Recently, the government approved new cotton varieties to be produced in the northern states of Punjab, Haryana and Rajasthan.

Bt Cotton and IPRs under India's Law

Bt cotton varieties being sold in India are not currently protected by IPRs nationally. However, this situation may soon change with the various revisions in India's IPR system. It is important for Indian policy makers to analyze the Indian case and the global IPR position relating to Bt cotton and evaluate the implications of granting IPRs in India on such technologies. Two IPR systems are relevant in the case of agriculture: patents and plant breeders' rights.

Patents

India's policy has generally been restrictive in terms of granting IPRs related to agriculture. India's Patent Law of 1970 did not allow patents on products including plant varieties, tissue culture, etc.[3] India also had no system of plant variety protection for decades. Thus, Bt cotton could not be protected under IPRs under this system. However, as mentioned before India's policy is currently undergoing a transition that would affect the Bt cotton issue as well.

India has undertaken major revisions in its patent regime by amending the Patent Act of 1970. The first amendment took place with the Patent Amendment Act of 1999, the second with the Patent Amendment Act of 2002, and India has currently passed the Patent Amendment Act of 2005. The major thrust of these amendments has been in the field of pharmaceuticals but the changes have implications for the agricultural sector as well.

The legal regime relating to patents for plants and particularly for transgenic crops is still evolving in India and also globally. There is enormous controversy on what should be the standard according to Trade Related Intellectual Property Rights Agreement (TRIPs) and among countries on the scope of such patents. In the case of plants, India's patent laws have been amended under the Acts of 1999 and 2002 to allow for process patents in the case of plants but not plants per se. Protection can be granted for treatment of plants, which renders them free of disease or increases their economic value .[4] Some authors point out, however, that this may *de facto* end up in patent coverage for plants.[5] Regarding biotechnological inventions in the case of plants it is not clear if the same would apply.[6]

The Patent Amendment Act of 2005 being passed in April, it is difficult to understand its full implications on agricultural inventions. It is reported that product patents for agricultural products are provided for while the question of patentability of micro-organisms and seeds has been referred to an expert committee.[7] The ordinance that preceded the Act did not categorically exclude seeds developed by novel means thus leading to speculation on the possibility of patenting transgenic seeds.

Clarity is lacking in this area, which may provide benefits diplomatically, but must eventually be sorted out in practice. To focus on some of the actual developments in the area of patents we can refer to some of the recent patent applications in India both with relation to cotton in general and patent applications filed by Monsanto.

Six patent applications related to cotton have been filed in India till December 2003.[8] Monsanto has filed seven patent applications related to plants in the same period.[9] A search in the patent database of TIFAC reveals that Monsanto has filed a total of 72 patent applications in India. The following table lists some of the significant plant related patent applications by Monsanto. Although none of the patent applications mention cotton in the title, Monsanto has filed one patent related to Bt.

Plant Breeder's Rights

India, for decades, had no system of plant breeders' rights. Thus no varieties of plants could be protected under plant variety protection in India, including Bt cotton varieties. India introduced the Protection of Plant Varieties and Farmers' Rights Act in 2001 to allow for plant

Table: Selected Crop Related Patent Applications Filed by Monsanto in India, January 1995-December 2003 (Abstract from Online Search on TIFAC Database on Patent Applications in India at www.tifac.org.in)

Title	Year of Application
Method for reducing pest damage to corn by treating transgenic corn seeds with pesticide	2003
Method for reducing pest damage to corn by treating transgenic corn seeds with Thiamethoxam	2003
Seed Treatment with combinations of insectides	2003
Seed Treatment with combinations of Pyrethins Pyrethroids Clothiandidin	2003
Seed Treatment with combinations of Pyrethins Pyrethroids and Thiamethoxam	2003
Nucleic acid molecules and other molecules associated with soyabean cyst nematode resistance	2002
Method of enhancing biological effectiveness of plant treatment compositions	2001
Compositions promoting chemical substances in plants	2001
Corn event PV ZMGT32NK603 and composition and methods for detection thereof	2001
Transforming plants to express Bacillus Thuringiensis Delta Endotoxins	2001
Expression of Fructose 1.6 Bisphosphate aldolase in transgenic plants	1998
Fungicides for the control of take-all disease of plants	1995

breeder's rights in India. One reason for introducing this Act was to conform to TRIPs by granting protection for new varieties. India also attempted to protect farmers' varieties and other varieties and designed a unique legislation. The Act enables registration under four categories: new variety, extant variety, farmer's variety and essentially derived variety. Under this Act, the Bt cotton variety marketed by Monsanto could be protected as a new variety. Applications under the Act are yet to be made public.

IPRs and Bt Cotton in the Global Context

Two patents relating to Bt cotton varieties called 926 B Pima and 930 B Pima have been acquired in the US as the box illustrates.

Implications of Granting IPR Protection on Bt Cotton Related Inventions in India

India must carefully weigh the costs and benefits of granting Bt cotton related inventions IPR protection in India. Implications of such IPR

Box: Patents on Bt cotton in US

Patent Numbers:
6,093,876 July 25, 2000
6,102,971 August 15, 2000

Sections from the Abstract:

The present invention relates to a method for rapidly introducing genes into germplasm which involves the use of crossing, backcrossing, intense selection and agronomic trait selection. The present invention further relates to two new and distinctive high yielding Pima Bt Bollgard.RTM. cotton cultivars, designated 926 B Pima and ***930 B Pima,*** which have been prepared in accordance with the method of the present invention.

Claims include:

Claims on Seed, Plant, plant parts, pollen, ovule, tissue culture, method for producing cotton cultivar seed.

Source: USPTO at www.uspto.gov; Purushothama, 2002

protection on farmers, public sector institutions and domestic companies require analysis. Measures to overcome any negative implications must be devised.

Extent, Scope and Nature of IPR Protection

It is important to evaluate what should be the scope of IPR protection. Broad patent claims may lead to difficulties in acquiring or negotiating many aspects of the plant in question. For example, if India permits similar type of patents which exist in the US related to Bt cotton, the broad nature of the claims would restrict our access to technology. According to Purusotama, "if we carefully try to analyse different claims, the inventors have all the rights on almost all the aspects of these plants. In the first place the varieties are patented, and even if we buy these, we are not free to use any part of this plant (leaf ovule, pollen) for further research without obtaining the original inventors permission. Even the technology to generate tissue culture plants of these varieties is patented and the seed which is developed by growing this variety is also patented".[10] A careful examination must be made when granting patent claims and mechanisms for transfer agreements and negotiations must be looked into.

The nature of the protection granted is also important in the case of plant breeders' rights. Under India's current law, claims could be made by firms, public sector institutions, NGOs or farmers on other varieties of cotton provided they can meet the set criteria. The interpretation of these categories could prove crucial in the coming years. In the case of Bt cotton varieties or varieties used in developing Bt cotton, a situation could arise where there are overlapping claims and disputes over ownership. This could block access and sharing of resources required for innovation.

Ensuring Access to Technology

Public sector initiatives to develop local Bt cotton varieties also must be kept in mind in deciding future policy. The public sector institutions in India have undertaken two major initiatives to produce Bt cotton locally.[11] These programmes utilized *cry 1a (b)* gene and the *cry 1a (c)* gene but were not very successful in developing Bt cotton.[12] Yet the Indian government wants to develop Bt cotton in the public sector because of the fear that private companies may neglect cotton varieties, may not fully meet the needs of the Indian farmer, and that the price of Bt cotton sold by firms may be too high for the small or medium farmer.[13] The *cry 1A (b)* and the *cry 1Ac* genes are proprietary and are being allowed for use for research purposes only.[14] Indian government must therefore address the issue of how to negotiate or develop agreements for ensuring that commercial varieties of Bt cotton can be sold by the public sector in future.

Private sector has also been attempting to produce Bt cotton in India. The IPR issues relating to Bt cotton may also affect the initiatives of domestic companies to produce Bt cotton. Swarna Bharat Biotechnics Private Ltd (SBBPL), Hyderabad, India, a consortium of seven Indian seed companies is attempting to develop Bt cotton.[15] The consortium has received licences for two genes derived from Bt from the National Botanical Research Institute (NBRI), Lucknow, India, for Rs. 7.5 ($ 0.16) million over a three year period and a royalty of 3 per cent.[16] With the introduction of novel Bt cotton varieties, SBBPL, which has a 30 per cent share of the total Indian cottonseed market, expects to claim some of the Rs 30 ($0.66) billion market per year that is at present monopolized by the joint-venture company Monsanto-Mahyco Biotech, Mumbai, India.[17] In order to promote indigenous efforts to commercialize Bt cotton, steps will be required to ensure access to technology in the future.

Farmers' Rights

The extent and scope of IPR protection should be closely evaluated in terms of its impact on farmers. India's plant breeders' rights law contains a crucial provision that farmers are allowed to save, exchange, use, and sell seeds of a protected variety but not under the breeder's registered name. India has attempted to make a provision to take care of farmer's rights to save and sell seed under the clause on Farmers' Rights, but this should not be negated either through amendments to the Patents Act, other policies such as the Seed Acts or through membership in international bodies such as UPOV. Some analysts have pointed out that the definition of 'branded' seed is unclear and since firms can identify a seed by its genetic makeup rather than the brand name, firms who intend to assert their IPR over their varieties could do so.[18] Although it would be difficult or impractical for multinational companies to attempt to restrict farmer exchange through legal means in India at present, it does not preclude such cases from arising in the future, nor does it mean that there are no other means of enforcing their proprietary rights if the situation so demanded.

Legal System in Practice

The actual functioning of the legal system must also be carefully observed. An interesting case of a patent on cotton being granted in India, though the law did not permit such patents, is illustrative. In 1987, Agrecetus, a multinational corporation, applied for a patent in India titled, "Genetic Engineering of Cotton Cells and Lines" and after examination the title was changed to, "Methods of Producing Transformed Cotton Cells by Tissue Culture". The patent was awarded in India in 1992. The patent created enormous controversy raising questions about the broad claim granting a monopoly on all genetically engineered cotton cells. It also raised a debate on whether genetic manipulation could be considered novel and therefore patentable. The Government of India initiated action after the patent was granted to get it revoked listing commercial and health reasons. After a hearing before the Joint Secretary in the Ministry of Industry the government issued a notification in 1994 revoking the patent noting that it was prejudicial to the public but not providing any further elaboration on the point.[19] In order to avoid such mistakes, the legal system must be monitored and redressal mechanisms must be workable.

Company Strategies

Finally, the reality on the ground on IPR issues will be shaped by how companies pursue their rights, and it is important to analyze these factors. It is reported that Mahyco has filed a case against Navbharat—the seed company that sold Bt cotton varieties without government approval while Mahyco-Monsanto awaited clearance for their variety—for infringing its intellectual property rights.[20] Yet, the case of these 'illegal' sales may have actually speeded up the clearance for Monsanto-Mahyco's Bt cotton. Monsanto has already co-licensed the *Cry 1Ac* gene to nine more Indian companies and Ranjana Smetacek, the company's spokesperson in India, says Monsanto welcomes the widespread usage of Bt cotton.[21] Since Monsanto is already concluding licences with various domestic companies, India could focus on ensuring that technology transfer takes place through careful negotiation. However, this should not blind us to the fact that Monsanto may contest the commercialization of indigenous Bt cotton in future, particularly if sales of Bt cotton from other sources or other cotton varieties cut into their market share.

The current focus on regulating the entry of genetically modified crops in India should not deter policy makers from paying close attention to the intellectual property aspects. The main reason for granting IPRs is as an incentive to invest. In the case of Bt cotton, investment is already underway, but steps are required for ensuring further investment and technology transfer. Whether this could be achieved through careful negotiations or IPR protection should be looked into. It is the right time to analyze what would be the real benefit in allowing IPR protection on Bt cotton related inventions at this stage, and ensure that in case IPRs are granted, such benefits materialize.

Endnotes

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[2] Indian Express, April 16, 2004.

[3] Subbaram, 1995.

[4] Ramakrishna, 2003.

[5] ibid.

[6] ibid.

[7] Indian Express, March 23, 2005.

[8] TIFAC, IPR Bulletin, 2004.

[9] ibid.

[10] Purushothama, 2002.

[11] Alam, 2004.

[12] ibid.
[13] ibid.
[14] ibid.
[15] Krishna, 2004.
[16] ibid.
[17] ibid.
[18] Ghose, 2003.
[19] Rao, 1999.
[20] Lalitha, 2003.
[21] Krishna, 2004.

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The Question of Patentability of Biotechnological Subject Matter: Issues and Options before the Policymakers

Dinesh Abrol*

Introduction

India whose patent act of 1970 was considered by many to be a model law for the developing world is now already on the way to make its national patent legislation fully compliant with the World Trade Organization (WTO) Agreement on Trade Related Intellectual Property Rights (TRIPs).[1] The process of amendment of national patent legislation has been controversial for the reason of making pharmaceutical substances and micro-organisms patentable.[2] In order to implement the new patent regime the government had to even divide the process of amendment of Indian Patent Act, 1970 into three instalments.[3] Throughout the transition period there was much public debate on the pros and cons of the possible outcomes of different amendments. The latest instalment of amendments is no exception; these were introduced in the form of an ordinance by the government because it lacked the requisite majority in the parliament. The Patents (Amendment) 2004 Ordinance was introduced on December 24, 2004 to become effective from January 1, 2005. It was criticised not only by

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the left parties but also by the sections of Indian pharmaceutical industry for being expansive on the issue of patentability of pharmaceutical substance and micro-organisms. Only after agreeing to make some of the key amendments, that the left parties were arguing for inclusion, the United Progressive Alliance (UPA) government could muster strength to press for a vote on the ordinance in parliament. Although the amended ordinance has been now adopted in parliament, the controversy continues in respect of the issue of patenting of biotechnological inventions. Even today it is not clear that how the controversy surrounding patents for biotechnological inventions is likely to be resolved in India. The question of patentability in relation to the exclusion of micro-organisms and the definition of pharmaceutical substances has been referred to the expert committee.

In India, controversy has surrounded the field of biotechnological subject matters from the time the TRIPs Agreement came to be accepted by the government in April 1994. India had five years to amend its national patent legislation. Legal provisions were explicitly included with the aim of determining the scope of patentability of biotechnological subject matter in the Indian Patent Act 1970 when parliament adopted the Second Patent (Amendment) Act 2002. The scope of patentability of biotechnological subject matter was defined amidst much controversy. The issue of from when India has to extend patentability to micro-organisms was itself raised quite strongly by the critics of the Second Patent (Amendment) Act 2002. It will not be out of place to also recall here that when the controversial legislative steps relating to the extension of patentability to biotechnological subject matters were being taken by the government to provide for the extension of patents to pharmaceutical and agrochemical products in 1995 through the amendment on exclusive marketing rights (EMR) to become effective from January 1, 2005, and to micro-organisms from the date of January 1, 2000 through the Second Patent Amendment Act, 2002, the concerned governments were even compelled to make promises that they would be later bringing in 2004 a final instalment of amendments to the Indian Patent Act, 1970 to introduce comprehensive legal provisions with the aim to define the scope of patentable inventions appropriately for India.

This article discusses the issues facing and options open to policymakers in the case of making their national patent legislations fully compliant with the Agreement on TRIPs in the area of biotechnology. It reviews the rationale of making biotechnological inventions patentable in the US history in particular from where the maximum pressure is being put by the powerful on the developing countries. It details out the issues connected with the scope of patentability of biotechnological inventions from the standpoint of developing countries which are likely to lose considerably by expanding and increasing the scope of patent protection in the case of biotechnological "inventions". Finally, the author offers a set of recommendations on the approach that a developing country like India can take to align its position with the developing world as a whole in respect of patenting of biotechnological inventions.

Patterns in the Patenting of Biotechnology: A Historical Perspective

To understand the pros and cons of the issue of how India should deal with the question of patentability of subject matters in biotechnology, first of all, it is necessary to ask what it is that makes up the subject matter of biotechnology to be so unique and controversial for the purpose of protection of intellectual property through patents. Two, for a proper assessment of the pros and cons of the possible approaches that India can take to tackle its international obligation of complying with the TRIPs Agreement we need to be clear about a) who needs what to be protected in respect of the subject matters, and b) what would be the impact of multiplying patent protection claims in biotechnology on public health, agriculture, human rights, development, scientific research, industry and trade.

The story of patenting of biotechnological "inventions" is only twenty years old. Prior to 1980, it was not clear that the patent law would be so accommodating. The Court of Customs and Patent Appeals (CCPA) in the United States (US) suggested as late as 1974 that a new strain of micro-organisms isolated from a soil sample was an unpatentable natural product and Congress's passage of the Plant Variety Protection Act 1970 indicated, at the very least, that the national legislature worried that the patent law in the United States did not permit the patenting of living things (Brennan, J., dissenting in the case of Diamond and Chakrabarty, cited by John M. Golden, 2001 on p 54). The law surrounding the possibility of patenting life forms and processes relating to the modification of life forms was not defined. The issue involved a variety of problems[4], but essentially boiled down, first, to whether living entities could be patented at all; and, second, to the scope of the claims that could be granted to such a patent.[5]

In order to describe the worldwide story of legal accommodation of biotechnological subject matter, it is necessary to discuss in particular the process of emergence of the legal position on biotechnology patents in the United States. The story of legal accommodation of biotechnology patents brings out that the law for biotechnology was not made in the US Congress but in the US Courts, and that these decisions were taken in the midst of a political environment that favoured market oriented governance in every sphere including knowledge. Further, it also tells that the accommodation of biotechnology in patent law has occurred at the cost of the application of the traditional requirements of patentability-novelty, industrial applicability, inventive step, enablement and patentable invention.

The story of legal accommodation of biotechnology in the US patent law is known to have begun with the well-known and widely cited 1980 United States Supreme Court case of *Diamond v Chakrabarty,* which rendered "new, human made, single-celled organisms" patentable in the 1980. This decision is known to have played a critical role in opening the way for the patenting of genetic material and its components.[6] It is also cited by the pro-strong patent lobby for the reason that in reaching this judgement the Court recalled the observation that emerged during the 1952 Congressional re-codification of the Patent law (U.S.C. 35) that the law should be expanded to "include anything under the sun that is made by man".

The fact of the matter is that the above said observation that the Chief Justice made is not citable as a decision of either the Court or the Congress on the patentability of naturally occurring living things. It is only an observation that Chief Justice Burger was making on the basis of the reports prepared by the US Congress at the time of the re-codification of the US Patent Act in 1952 to argue the case of patents for "non-naturally" occurring living things. The observation of Chief Justice Burger has no linkage with any of specific decision taken by the US Congress on the patentability of naturally occurring living things. The above cited expansive statement that the Chief Justice Burger made in connection with non-naturally occurring organisms to expand the scope and accommodate the said subject matter as patentable invention was only based on the Report of the Congressional Committee.[7]

Similarly, many scholars also cite the Chakrabarty decision as a case where the US Courts overturned the earlier doctrine which excluded biological organisms and genetic material from eligibility on the grounds that they are a "product of nature" and replaced this with what may be called the "hand of man" doctrine. But it must be realized that the decision in this case is in no way related to the question of patentability of the purified and isolated living things. The US Supreme Court is not known to have taken ever a decision in favour of gene patents or patents for purified naturally occurring micro-organisms.

However, it is true that the US Courts have since long determined that new molecules and, in general, artificial variants of naturally occurring substances are patentable. In 1979, the CCAP had itself extended the "greater purity" rationale to biological products, endorsing the view that a particular pure bacterial culture was a "product of a microbiologist", rather than a product of nature. Even in the case of this decision it must be recognized that the CCPA decided on its own the issue of gene patenting. The CCPA rejected the products of nature doctrine in *In re Bergy* and observed that "the biologically pure culture of claim 5" clearly does not exist in, is not found in, and is not a product of "nature". It is man made and can be produced only under carefully controlled conditions. The CCPA's decision is limited, as the court did not decide whether all living things are patentable subject matter. Having no precedents or principle-based arguments, the CCPA arbitrarily asserted that it was in the public interest to include micro-organisms within the terms "manufacture" and "composition of matter".[8]

In the US, these decisions, however, did set the stage for a decade of aggressive expansion of biotechnology patenting. In the political environment that prevailed during this period, the patent law was considerably weakened in respect of its extension to biotechnological subject matters. The new Court of Appeals for the Federal Circuit is credited with helping to weaken the traditional requirements of novelty, utility, non-obviousness, enablement (disclosure) and patentable invention as well as with helping to allow patents forever-wider ranges of subject matter. Practically speaking, there is not much left to constrain the patentability of biotechnology with regard to the "product of nature", novelty, and enablement doctrines in the US.[9] With regard to the patenting of biotechnological subject matter, the courts have been loosely applying the standards of utility and non-obviousness to appear pro-patent. In the US, throughout this period the standard of non-obviousness remained also a serious problem in the case of biotechnological inventions because in the US the standard revolves around whether the invention was "obvious" at the time invention was made to a person having ordinary skill in the relevant art. Given this and other limitations of the standard pertaining to non-obviousness, it has been quite easy for the Courts to surrender to the pro-patent wave and acknowledge the patentability of another biotechnological invention. The USPTO's new guidelines seem to have responded to the emerging crisis of patentability in respect of biotechnology a bit better by specifically invoking Brenner as part of a reaffirmation of the need for either "well established" or "specific and substantial" utility.[10] But as also suggested by Golden that they are not enough something more is desirable. Deceleration of expansion of patentability is highly necessary.[11] It would help the process of technical advance. It would help to ensure that a functioning, and to all appearances highly successful, system of public sector research would retain access to the fundamental products of publicly funded science. Even the biotechnology industry has a stake in the balanced system if it is made to realize its long-term interests in the field of biotechnology. In the latter part of this paper when the economics of biotechnological innovation is discussed we also bring out how a balanced system of IP protection is in the interest of everyone including industry.

The number of patents for biotechnological "inventions" has been continuously increasing since the beginning of the eighties in the United States, when it was made clear that they were patentable. Patents for genetic inventions have skyrocketed in recent years.[12] Despite that growth, controversy surrounding biotechnology patenting has not even died in the US. Arguments against patentability continue to be invoked by the critics of the prevailing patent system. These arguments are either based on ethical reasons against the provision of exclusive rights over living organisms, the human body or genetic material, or on economic or legal reasons linked to the difficulty of drawing a line between inventions and discoveries of natural phenomena.

Status of Patentability of Biotechnology

Today in all these countries biotechnology covers three types of subject matters and these are: the biological matter itself which includes the products of biotechnology; the methods and processes of making the biological matter and/or the products, and; the uses of the biological matter or the products of biotechnology. The biological matter itself includes both living as well as non-living matter. "Non-living" biological matter includes amino acids, peptides, proteins, fats and fatty acids, and nucleic acids. These kinds of compounds are better recognized when referred to by their commonly known names of anti-bodies, hormones, enzymes, antibiotics, steroids, cholesterol, and DNA molecules. Most of biotechnology is currently directed at producing these "non-living" products. At the heart of modern-day biotechnology is the ability of these "non-living" products with the help of vectors to penetrate a cell and be involved in and direct the "genetic manufacturing".

Regarding the status of patenting of these "non-living" genetic materials, all of these are being patented as just chemical compounds. By patenting them as just chemical compounds, it needs to be reiterated that their special nature is being completely ignored by the policymakers. In the race to rapidly patent them today, the criteria of patentability are being diluted as later discussed in the paper in detail. In the normal course, none of these "products" are considered to be "living" biological matter. However, in our view, these cannot be treated as merely chemical compounds; all of these chemical compounds are part of living entities.[13] The identification and separation by conventional methods of genes that code for well-known compounds represent a discovery and not an invention.

Beyond the structural non-living components of living organisms are the smallest, wholly viable units of life called cells. Cells are also the smallest reproducible units of life, and it is this aspect of reproducibility, which is completely unique to invention in biotechnology. Cells come in all different shapes and sizes and have differing capacities for independent survival. Microbes, for example, are unicellular organisms capable of living in the environment. They are found in the environment and are often a part of inventions-which are maintained as biologically pure isolates from soil. Human, animal or plant cell lines, existing as individual cells isolated from the whole organism, are completely dependent on laboratory generated medium and culture conditions for survival.

Regarding the current trends in patenting of biological matter including products, the attempt is to accommodate somehow the biological matter by bending the patentability requirements. Trends indicate that there is not much traction retained for the traditional patentability requirements in the case of US patent law. As discussed in the previous section, practically speaking, not too many constraints are now left with regard to the "product of nature", novelty, and enablement doctrines.

The methods and processes of manufacture in biotechnology are the next most important subject matter of biotechnology. The more commonly known types of processes, which are included under the rubric of biotechnology, are fermentation processes, chemical and diagnostic processes as well as methods of treating human or animal bodies and methods of controlling pests. It also includes methods and processes for the creation of products of cells such as hormones, enzymes and the like. The area of methods and processes has raised a number of issues because the techniques that are available provide the potential for creation of genetically altered biological matter itself. The methods and processes of manufacture in biotechnology are distinguishable from other fields of subject matter in that most of the actual process is carried out by something other than man. A living organism, e.g. a bacterial cell, or a biological compound, e.g. an enzyme, does the "work". The method is really more of a recipe for success in preparation of the product. The inventor simply identifies the correct combination, sequence, conditions, etc., but the intrinsic properties of the chemicals are responsible for the product.

Finally, there are inventions which deal with what is done with the products of biotechnology. In this respect, the exceptions have been developed in the case of medical treatments involving therapy, surgery and diagnosis for human beings and animals. Method claims are already excluded in several jurisdictions. Otherwise, the limitations placed by patenting in biotechnology are not very different from the problems of absolute monopoly that we are already encountering in the case of pharmaceutical product patents.

Historically, much of the difficulty in using recombinant DNA techniques has consisted in locating, isolating, and sequencing the genes associated with particular proteins. However, advances in technology and in laboratory techniques have eased and automated much of this process, substantially routinising a variety of tasks that had previously required considerable effort and ingenuity. Indeed, automation has made possible the DNA sequencing of whole species to be undertaken in a short period; researchers using automated sequencers have already been able to sequence the genomes of a number of small species and the sequencing of others has become only a matter of attention and time. With sequencing reduced to routine and with the results of the Human Genome Project (HGP) and other public sector genome projects being placed in information repositories freely accessible via the internet, it is expected that the next several years will witness a shift in the focus of genetics research toward the more inherently intractable problems of understanding gene and protein function, problems expected to occupy biotechnology researchers for decades to come.[14]

Further, the completion of an increasing number of genome maps has led to the realisation that genomes are much smaller, in terms of the number of genes within an organism, than had been previously thought and that there are significant genetic similarities or "homologies" across species, genera and classes of an organism. This is reconfiguring scientific understandings in two important ways: a) the rise of phylogenetic taxonomy and system biology is increasingly leading to an emphasis on the relatedness between organisms, including proposals to extend the genus Homo to include chimpanzees; b) the completion of the first genome maps has revealed that the differences in the order of biological complexity between a nematode worm, a mouse, and a human being can only be explained by the realisation that one gene may encode multiple proteins. The nature of genetic homologies between organisms signifies that first of all, intellectual property claims in relation to the biological or genetic components of one organism may permit intellectual property claims in relation to the biological or genetic components of other organisms (i.e. primate embryonic stem cells and human stem cells). Furthermore, given that it is now known that single genes are involved in the expression of multiple proteins, permitting that patent claims in relation to DNA and genes is likely to have unforeseen consequences for science and innovation as science moves into the realm of proteomes where key developments in relation to healthcare are predicted.[15]

Further, in biotechnology especially many of the results of research are not merely discoveries of facts but creation of research tools (such as for gene manipulation, gene mapping and analysis of sequences). A large number of the research results in the biotechnology field are in effect research tools that are by their nature of potential use to other researchers. To patent a vital research tool, now treated as a technological advance, forecloses the possibility that others can pursue research with in the fields that need it. As tools can be very basic and generic, this seems to pose a serious threat to scientific progress. In the context of research tools, the scope of the experimental use exemption has been generally limited to pure and non-profit research, which is certainly insufficient to protect in the developing countries the interests of future R&D.

Possible Approaches to Restrictions on the Scope of Protection

Keeping these developments in view, it would not be wrong to conclude that the current trends in patenting of biotechnology, where the attempt is to accommodate somehow the biological matter by bending the criteria, norms and standards of patentability, are quite problematic and are not in the interest of either science or innovation. They are inimical to the public interest, be it of the developing countries or of the developed world.[16] In the developed world, the practices being followed at the moment are clearly failing to recognise this public interest.

In our view, as far as the issue of what approach the world needs to take as a whole is concerned, first of all there is need to recognize that biotechnology involves essentially the production of useful products from one or more of the basic components of living things, including living micro-organisms, tissue and cell cultures, proteins, genes or DNA, and that the processes and products of biotechnology cannot be strictly reduced to the hand of man. In biotechnology, living organisms do the "work". The issue of reproducibility remains to a large extent still alive in the case of biotechnology inventions. Strictly speaking, the patent authorities could easily exclude many technical advances in biotechnology from the scope of patent protection even for the reason of poor enablement. For this and other reasons many scholars have therefore argued in the past that biotechnology needs a *sui generis* legislation for legal protection of intellectual property. But the feasibility of introducing altogether a new *sui generis* legislation for biotechnology is going to be a far more serious problem than playing within the patent law for balance. It is yet to be seen how the discussions on TRIPs in the WTO and on patent law treaty in the World Intellectual Property Organisation (WIPO) are finally going to take what kind of turn for the developing world.

Thus, at the moment, besides making licensing less costly and free (not at all discussed in this paper), which is an absolute necessity in the case of biotechnology patents, narrowing of the scope of patent protection is the most important solution. Even in the US strengthening the utility requirement appears to be the best way to restrict patent monopolies through patentability's traditional threshold requirement.[17] Discussions on the possible radical revival of a broad product-of-ban nature indicate that the proposal to revive a strict and strong product-of-nature ban can get into problems on account of not only the political economy reasons but also due to the intrinsic difficulty of drawing any line between the "natural' and the "artificial".

Carvalho, Deputy Director and Head of the Industrial Property Law Section, Economic Development (Intellectual Property Law) Department, WIPO, Geneva, offers an important alternative to make the implementation of this radical proposal possible and takes care of the exclusion of gene patents or of patents on living things to a large extent within the scope of doctrines that are already established in the US. He suggests that gene patents are not, nor should they be, patentable subject matter. Alternativeness is the first of four substantive conditions of patentability (the most critical condition and is implied always in the first test on patentability that we carry out to distinguish discoveries from inventions). In his opinion, genes, as an invention of nature, rather than of man, fail to meet the condition of alternativeness. He argues that creations, like genes, that cannot be alter-invented, undermine the social value of the patent system. He suggests that the attention of law-makers and policy-makers must be drawn towards the risks of granting patents for human genes, both in their natural environment and after being identified, isolated, purified, and synthesized. He argues that these advances are close to discoveries that cannot be alter-invented. [18],[19]

In our view, Carvalho is offering an approach that is feasible and can solve effectively to a large extent the issue of how to go about narrowing the scope of patent protection at the level of invention itself. Regarding the criteria of non-obviousness, we do not need to follow the US. There is no worldwide acceptable practice regarding the determination of inventive step or non-obviousness and the scope of utility or industrial applicability. As a result it is very much possible to work out, practically speaking, our own tests and guidelines in respect of these two criteria besides altering the perspective on the question of patentable invention with a view to exclude discoveries.

The Costs and Power behind Legal Accommodation of Biotechnology

Since the powerful have had their way to include them as of today into the existing patenting regimes by diluting the tests concerning patentability without bothering much about the consequences it can have worldwide for science and innovation, it is necessary to understand the power of forces behind patenting and to analyse the costs and benefits of their actions including for themselves. As discussed above, the story of biotechnology patenting originated from the United States. In the United States, the biotechnology industry's growth has been connected with the conception of "entrepreneurial science". The role of patent law for biotechnology is aptly described for the US biotechnology scene by John M. Golden when he states that "after all, for any conception of "entrepreneurial science" to flourish, it requires something to sell. In the United States, patent law provided young biotechnology firms with one of their few "assets"-saleable intellectual property rights in some of the most fundamental constituents of life". See also V. Walsh, 2001 and B. Coriat and F.Orsi, 2001 for the description of the connection of the changing political environment in the beginning of the eighties in the English-speaking countries.[20]

Most important to the birth of the modern biotechnology enterprise in the early 1970s was the development of genetic engineering. This development made possible a new industry that promised to use cutting-edge science to produce a new generation of diagnostic techniques, treatments, and cures. Entering where opportunity generated by genetic engineering had knocked, a host of small biotechnology firms began arising around research universities in the United States (US). While these dedicated biotechnology firms (DBFs) appeared and developed in the United States, the federal government also chose to revaluate its approach to the promotion of science and technology. The government's eventual shift to a "cooperative model" of academic, industrial and federal research fitted the needs and mindset of the biotechnology industry. Patent law itself was modified to serve the biotechnology industry's needs that were themselves also a product of the conditions prevailing in the United States concerning the organization of finance for innovation through the development of venture capital. Under the influence of a new federal appellate court and a series of legislative changes, patent law was modified, producing doctrines and policies to provide enforceable property rights in a substantial share of the purified natural substances that were biotechnology's most characteristic products.

The recognition and enforcement of strong intellectual property rights has been identified by many observers to be an important factor contributing to the growth of biotechnology in the US. In particular, these observers refer to the post-1980 connection of biotechnology developments with the emerging intellectual property scene in the US, which is that the establishment of clearly-defined property rights has played an important role in the explosion of new DBFs. They point out that since, by definition, few firms had complementary assets it is the presence of strong patent rights that enabled them to appropriate returns from new science. DBFs have been primarily university spin-offs that mobilise scientific and technological knowledge and transform it into potentially commercially useful techniques and products. These firms have been usually formed through collaboration between scientists and professional managers, backed by venture capital. Their specific skills reside in the knowledge of new techniques and in research capabilities.

We also know that Milstein and Kohler's groundbreaking discovery-hybridoma technology-was never patented, while Stanford University filed a patent for Boyer and Cohen's process in 1974. Boyer and Cohen renounced their own rights to the patent but were nevertheless strongly criticised for having been instrumental in patenting what was considered to be a basic technology. Similarly, growing tension emerged between publishing results versus patenting them. Whilst the norms of the scientific community and the search for professional recognition had long stressed rapid publication, patent laws prohibited the granting of a patent to an already published discovery. Research in genetic engineering was on the borderline between basic and applied science, conducted primarily in universities or otherwise publicly funded, and the degree to which it was appropriate to patent results of such research became almost immediately the subject of controversy.

Nature of Technical Advance and the Question of Determination of Scope of Patent Protection

It is also necessary to keep in mind that the fundamental rules of patent law were set in a world in which inventions were mainly mechanical and intellectual creations and were not protectable unless good cause was shown. Patenting was confined to the protection of discrete products. Technical advance was far less rapid. The scope of protection was not a major issue for mechanical inventions because it was mostly possible to invent around the discrete products. In the case of chemical technologies, where to a large extent chemical product invention tends to fit the 'discrete' model, the scope of protection came to be a controversial matter only because pharmaceutical product patent leads to the emergence of a monopoly, which cannot be tackled by inventing around the product. In the case of pharmaceutical products, since there is a one to one correspondence between the structure of molecule and the therapeutic effect product patent tends to provide absolute monopoly. However, in a number of technologies, the pattern of technical advance is not discrete. The pattern of technical advance is mostly cumulative. Evidence indicates that in a number of technologies where the pattern of technical advance was cumulative the patent system acted as a drag on the pace of technology development.[21] Their case histories demonstrate that there is much more at stake in the cumulative technologies than in those in which inventions are discrete. Analyses of the effects of protection open up a much more complex set of issues than considered by the simple trade off model where analysis is in terms of incentives to innovate to a single inventor (actor) versus the inefficiencies from market power. In the case of cumulative and science based technical advance the issues are complex when it comes to the question of scope of patentability of subject matter. At any time many actors may be in the invention game, and that the game may have many rounds.[22]

In biotechnology, right from the beginning the pattern of technical advance has been driven by science based technological developments.[23] However, it appears that due to the intensification of (increased role) of scientific advances in the innovation process significant changes are today underway. The science-based models of biotechnological innovation are today faced with the task of coping with the systemic nature of technical advance.

For example, in biomedical research the process of technical advance is undergoing a paradigm shift from gene-centric biology to genome-centric biology that changes the way we think about biological innovation, genetic information, and the way biologists do their work. The shift to genomic-centric biology is creating a hybrid model of discovery and innovation in which the creation of new ideas and products remains the dominant strand but the supply of new inputs such as databases and software are becoming increasingly important to the process of innovation. The genetic information being derived from research on the genomes is extremely valuable, both for basic research and for commercial purposes, even if few commercial products have resulted. Thus, the core business of an increasing number of new market entrants in genomics is information, not sale of drugs or diagnostics. The entrance of a host of gene information firms, such as Human Genome Sciences, Incyte, and Sequena, along with new entrants to other parts of the discovery pipeline, has shifted the market structure and upset many of the traditional economic assumptions about innovation in new drugs. The growing intersection of this new genomics framework with IPRs already is profoundly reshaping the balance struck among the interests of biomedical researchers, private sector market participants, and the public good.[24]

Given these changes, the first big problem emerging before the law and policy makers is how to assure a sufficient supply of genomic information through research. When the tendency is to patent early in the process of innovation, it is not going to be easy to assure the supply of genetic research. Excessive protection early in the innovation process can impede innovation at later stages. Further, public sector and open science are alone a reasonable pre-condition for the supply of genetic research. The public sector system for deploying funds and values still constitute the core of the American system for producing biotechnology-related innovation. All the professionals who contribute to innovative research in the system of biotechnology innovation are dependent on their training and education on the public sector system set up for biotechnological education and research in the US.

The related overarching problem, often overshadowed by the initial issue of producing enough genomics knowledge, involves the distribution of genomic information. Genomics research is a "cumulative systems technology" marked by an interactive and cumulative process of discovery and innovation that builds on an accumulated stock of genetic knowledge developed from numerous sources. Genomic innovation is also characterized by its growing divergence from either the single inventor/absolute novelty approach to innovation that continues to dominate patent law. From a legal perspective, granting private property rights to genomics information may increase transaction costs because researchers and users confront the problem of determining who owns what, how to secure rights in a timely and efficient way and at what price.

In the current context of innovation, even from the standpoint of encouraging investments from small companies (for playing the role that DBFs performed for the field of biotechnology in the US) strong and broad patents do not make sense. Evidence suggests that DBFs own official documents call into question the extent to which patents should and do form a reliable basis for investment: Sec filings routinely discourage investor reliance on biotechnology patent claims. In addition, a history of wild, short-term swings in biotechnology stocks, often irrespective of individual firms' patent positions, calls into question the efficacy of patents as a means of ensuring stable investment. There are alternate ways available for financing the small companies in a rational way; the successful experience of Europe is an example where alternate means of financing have been available. The experience of non-English speaking countries, like the Netherlands, Ireland, Germany and France, is relatively speaking a positive example of how successful small companies can be brought into the financing system. It is not to be forgotten that the stimulation of fights over IPRs, such as through patent litigation, distracts from, and increases the cost of, the pursuit and development of innovations.

In the current context of innovation, it is not possible to wish away the problems for small companies. Their litigation costs are likely to grow manifold under such circumstances. Biotechnology patent litigation cost is generally recognised to be high. Corruption of the public sector values and the existence of vested interests of the small companies can jeopardise the quality and objectivity of research. Another important concern relates to the health of biotechnology industry itself. Downstream companies, which have their own interests in ensuring that scientific researchers can work freely, have themselves begun to battle the ever-expanding bounds of patentability. In 1998, several pharmaceutical companies agreed to pool funds in an effort to identify single nucleotide polymorphisms (SNPs), the most basic markers of genetic variation, and to place information about them in public domain. Over-aggressive patenting could ultimately favour unnaturally large firms; small firms' advocates know very well. Bigness in the plant biotechnology industry is one such experience of the developed world. In pharmaceutical industry, we have seen mergers and takeovers growing. And remember this that the big pharmaceutical and seed companies are bound to deter the entry of developing countries' firms into the field. Strong and broad patents are therefore far more dangerous in the current context of innovation for the developing world as well. Patents are not the only tool in the kit that the developing world needs to stimulate investment in innovation. Even in the case of India where the strength in the field is adequate to enter into the arena strong and broad patents are not the need of the industry.

Take the case of pharmaceutical industry where domestic firms are capable of pursuing a) marketing biopharmaceuticals for foreign firms in order to test waters (market development based on imported recombinant products; b) producing diagnostics (production is currently import intensive); c) researchers or industrialists with venture capital support or foreign capital into DBFs establishment for contract research, production of biological products and chemicals using rDNA technology; d) speciality chemicals producers getting into production of chemicals using rDNA technology; and e) integrated pharmaceutical strategy using foreign companies for drug development partnership. For none of these, strong and broad patents are needed by domestic firms to get into positive relationships with the foreign firms. In these areas, domestic firms are equivalent to service providers. The main services to be provided are in the sphere of either contract manufacturing or contract research. In the sphere of contract research, services are related to bioinformatics (software outsourcing/data base creation services) and clinical research management. Even drug discovery research in contract mode consists of getting clones of constructs and expressing them and genomic/ proteomic target test. This task based activity needs the entrepreneurs to respect confidentiality and quality behaviour. In the case of such activities, professionalism, trust building and contract non-breach matter most to the partners. Strong and broad patents are neither asked for nor are they of any help.[25]

Even for the export of generics to the markets of developed countries strong and broad patents will not increase incentives for domestic firms. In fact, the pursuit of ever greening that is occurring today in the markets of developed world that needs to be stopped if the local firms are to succeed in the export of generics. In general, local firms from the developing world need a patent system, which provides flexibility to them for the perusal of competence development for manufacturing and research. Opportunities for competence development need a patent system, which would correspond to their existing stage of development. Finance capital (stocks) driven patent system, which is hungry for privatization of knowledge and consequently for strong and broad patents, is in fact inimical for the development of productive capabilities in the current context of innovation.[26]

Conclusions

In the case of biotechnological inventions, it is in the interest of developing countries to argue for the narrowing of scope of patent protection. Argentina tried it, but its economic crisis led to the government later succumbing to the US pressure on the question of micro-organism exception and exclusion of gene patents.[27] India is in stronger position to bargain with the powerful countries. It can take steps to exclude several important subject matters, like naturally occurring micro-organisms, even when isolated and purified, gene patents, etc., from the scope of patentability based on the grounds of doctrines already discussed in the paper. It will help the country to align itself with the countries from Africa and Caribbean group better because they are opposed to providing patents for life forms.

It will also give a reinforcing influence to the negotiations on benefit sharing in the context of negotiations going on in the forums of CBD, WIPO and WTO. This position is relevant to the task offered to the expert committee set up to deal with the question of patentability of micro-organisms and pharmaceutical substances including the products of biopharmaceutical industry. The committee should take this broader context into account and not listen just to the big players of pharmaceutical and seed industry who think that they might benefit from the inclusion of these important subject matters into the scope of patent protection.

It is the larger public interest and longer-term interest of industry and nation that must guide the policymakers and lawmakers at this important moment.

Endnotes

[1] The Patent (Amendment) Act 2005 was adopted by the Lok Sabha on March 24, 2005 in the last session of parliament.

[2] The bill in the form it was moved was unacceptable to the left opposition. The Bhartiya Janta Party (BJP) and others walked out at the time of final vote. The left accepted the bill after it was amended by the government in respect of a number of provisions relating to definitions, patentability, EMR and compulsory licensing.

[3] The latest amendment happens to be the third instalment of amendments moved to the Indian Patent Act 1970 to make it fully compliant with TRIPS Agreement.

[4] See OTAF, 1984.

[5] Merges and Nelson, 1990.

[6] For an accessible interview based discussion of the case see, Kevles, D (2002) "A history of patenting life in the United States" with comparative attention to Europe and Canada.

[7] Congressional Committee Reports S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952) (United States Congress, 1952).

[8] Shankar, 2004.

[9] Once a product is shown to be "non-natural", the novelty requirement is hardly a hurdle. Biotechnological inventions can be easily shown to possess the characteristics of originality and priority. Likewise, although the enablement requirement does place some constraints on inventive behaviour, it does little to regulate the patentability of biotechnology per se, unless used as a cover for enforcing the requirement of utility.

[10] USPTO Utility Examination Guidelines, 2001.

[11] See NCB, 2002 and Golden, 2001.

[12] OECD Review, 2004.

[13] Nucleic acids (two major types: DNA and RNA) are the basic building blocks of genetic materials. It is the deoxyribonucleic acid (DNA) that stores the complete genetic information required to specify the structure of all proteins of the organism and to determine the individuality of the organism. All of the genetic material, which defines an organism, is known as genome of the organism. DNA, which is ultimately responsible for the synthesis of proteins, is contained in the nucleus. Most protein synthesis occurs in the body of the cell (the cytoplasm) outside the nucleus but inside the cell of the wall.

[14] Golden, 2001.

[15] Paul Oldham, 2004.

[16] See Abrol and Menon, 1993 for further discussion on the problems and consequences of strong and broad patents.

[17] Golden, 2001.

[18] They provide alternatives to existing technology that can be alter invented to obtain a different, non-overlapping and non-equivalent solution for the same technical problem.

[19] Nuno Pires De Carvalho, 2004.

[20] In the year 1980, on the whole biotechnology was beginning to appear as new technological opportunity-or-threat from outside the industry, first commercialised by new entrants, start-up firms which typically were established to commercialise public sector research in molecular biology and the life sciences more generally, that had been funded by initiatives such as the 'War Against Cancer'. Vivian Walsh adds that the appearance of the start up firms was given some encouragement by a number of developments in the political environment. An ideological movement against state intervention and in favour of the increasing markets as the most efficient way of governing an economic system, especially in the English–speaking countries, was further encouraged by the election of the Thatcher Government in the UK and the Regan Administration in the US in 1980. Market relationships were extended into previously non-market sectors of the economy, which together with final deregulation, encouraged the development of venture capital markets and other institutional changes designed to promote market mechanisms, the privatiation of public sector research, and a growth in the number of start-up firms.

[21] Evidence exists that the Wright patent – an efficient stabilising and steering system-significantly held back the pace of aircraft development in the United States. In this case and others, when blockages arose industries did not automatically turn to the deadlock-breaking solutions, patent pooling and cross licensing.

[22] See Nelson and Merges, 1992 for further details.

[23] The term biotechnology was first used in 1919 to describe the process by which industrial products were produced from agricultural raw materials with the aid of living organisms. The most important application was fermentation techniques used in brewing. In the 1930s, molecular biotechnologists began doing research on organisms below the cellular level. Today's biotechnology derives from these scientific advances. Four key scientific advances led to today's biotech industry. In 1938, DNA was identified as the carrier of genetic information. In addition, researchers discovered that microbes could exchange genetic information. In 1953, the second most important advance in biotechnology came through on account of the discovery of the double helix structure of DNA. This led to an understanding of how DNA transferred genetic information to cells. In 1973, researchers at Stanford and Harvard demonstrated how to stably insert genes from a foreign organism into a host structure. The Cohen-Boyer gene splicing technique made genetic engineering possible. Recombinant DNA (rDNA) techniques of Cohen-Boyer led to production of hybrid gene material. Milstein and Koehler invented hybridoma (fusion) technology, which allows the combinations of nuclei and cytoplasm from different cells to combine desirable characteristics of each.

[24] See Clara Long, 1998 for further discussion.

[25] See Abrol 2004 for more details.

[26] The kind of finance driven patent system that the developed world has put in place is allowing the firms to dissuade the arrival of firms potentially rival by the announcement of patent registrations which play in fact the role of bait in their fields of privileged competence (strategy said with the "minefield" or with the "porcupine") or to try to obtain the widest possible protection on their discovery, with the aim of dissuading competitors' possible arrival. The firms can adopt all the more easily such strategic behaviour as the novelty of the rights of patents for living entities leaves an important margin of interpretation, which they can try to manage in their advantage (See Coriat and Orsi, 2001 for more on the problems with finance driven model).

[27] See Shanker, 2004

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Biotechnology, Cartagena Protocol and the WTO Rules

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Introduction

Since the early 1990s, biotechnology, intellectual property rights (IPRs) and the related policy have become extremely contentious areas of discussion at national and global levels. Historically, these areas were domains requiring specialists with specific training and skills to practise. However, recently these issues have become critical to several discussions on conservation and development. Recongnising the impacts of these two specific areas in development, several countries have started addressing them from several angles – economic, social, environment and political.

The Convention on Biological Diversity (CBD) is one of the three multilateral environmental agreements (MEAs) that was adopted as a result of the Rio Earth Summit in 1992. About 189 countries are Parties to the CBD, agreeing to implement various provisions of the Convention. Also, the CBD is one of the key trade-related MEAs that aim to promote the conservation and sustainable use of biodiversity besides sharing the benefits of such use equitably. One of the significant outcomes of the discussions under the CBD has been the adoption of the Cartagena Protocol on Biosafety (hereinafter, the Protocol) which was adopted after six years of tough negotiations in January 2000. The Protocol is based on the precautionary approach and establishes core procedures and a set of standards relating to the import and export of LMOs to ensure that the Parties are able to make informed decisions.

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The World Trade Agreement is a set of internationally binding Agreements negotiated under the WTO. As of now, WTO has a membership of 146 countries and customs territories. The WTO rules are designed to liberalize market by removing unnecessary, discriminatory and protectionist barriers to free trade.

WTO has been discussing the need to address issues of environmental concerns of trade practices for a long time. More recently, the 4th Ministerial Conference in Doha agreed to launch negotiations on certain aspects of the trade and environmental linkage. This was followed by the Ministerial Declaration at CBD COP6 to the CBD and Plan of Implementation of the World Summit on Sustainable Development (WSSD) who all reaffirmed the importance and the need to design and implement mutually supportive activities with other conventions, international organizations and initiatives.

A quick review of CBD obligations to trade reveals the fact that even though the word 'trade' is not mentioned, several Articles relate to trade and associated issues (Table 1). Several decisions of the Conference of Parties relate to trade like the COP 5 decision V/6 on applying an ecosystem approach to conservation that mentions that any ecosystem management programme should:

a. reduce those market distortions that adversely affect biological diversity;
b. align incentives to promote biodiversity conservation and sustainable use;
c. internalize costs and benefits in the given ecosystem to the extent feasible.

A similar review of WTO obligations relating to biodiversity and environment provides mechanisms to address issues of trade and the importance of biodiversity (Table 2). The Doha Ministerial Declaration has implications for environment as well as biodiversity, especially on issues dealing with tariff and non-tariff barriers.

Biotechnology and IPRs

Article 27.3 (b) of the TRIPs Agreement deals with IPR protection of life-forms. While the TRIPs Agreement only sets minimum standards;

Table 1: CBD Obligations relating to Trade

Article	What it says
Preamble	Calls on Parties to adopt a precautionary approach.
Article 6 (b)	Requests sectoral integration of conservation, sustainable use and benefit sharing issues.
Article 8 (h)	Calls for preventing introduction of invasive alien species besides their control and eradication.
Article 8 (l)	Calls for regulating or managing processes and activities that will have adverse impacts on biodiversity.
Article 10 (b)	Calls on Parties to adopt measure relating to use of biological resources to avoid or minimize adverse impacts on biodiversity.
Article 10 (d)	Calls for protection of customary use of biodiversity that is compatible with conservation and sustainable use.
Article 11	Calls on Parties to adopt economically and socially sound measures that act as incentives for conservation and sustainable use of biodiversity.
Article 14	Calls on Parties to establish sound environmental impact assessment methodologies.
Article 15	Establishes the rules on access to genetic resources and equitable sharing of benefits arising out of such use.
Article 16	Calls for the transfer of technologies, considering the IPRs.
Article 19	Calls for measures to ensure safe use of biotechnology.
Article 22	Relationship with other Conventions.

members may, but shall not be obliged to, incorporate into their law more extensive protection than that required by the TRIPs Agreement. Discussions under Article 27.3 (b) are still on with countries understanding and responding to the provisions in varied ways.

Related to conservation of biodiversity, Article 27 (2) enables member states to avoid or limit patent protection on plants to the extent that patents could adversely affect genetic diversity by accelerating genetic erosion.[1] However, it is inconceivable that such exclusions or limitations should be based upon Article 27 (2) of TRIPs, given the fact that Article 27 (3) of TRIPs explicitly allows the exclusion of plants in general. Furthermore, Article 27 (2) only allows the exclusion of inventions whose "commercial exploitation" is necessary to be prevented; it does not seem to allow exclusions where the mere patent itself could have adverse effects.

TRIPs require micro-organisms to be patentable, while plant variety rights must come under some kind of IPR system, but not necessarily under patents. Countries are still divided on the issue of patenting

Table 2: WTO Obligations relating to Biodiversity

Issue	What it says
Preamble	Commits for sustainable development and to protect and preserve environment.
Article 6 (relevance to Agreement on Agriculture)	Provides framework for reducing subsidies, but exempts certain environmental activities.
Article 2 (relevance to SPS)	SPS measures to be applied only to the extent necessary and not to be applied without scientific evidence.
Article 3 (relevance to SPS)	Expresses presumption of consistency for international standards.
Articles 3.3, 5 and 5.7 (relevance to SPS)	Risk Assessment procedures as relevant to Member's needs.
Article 2.6 (relevance to TBT)	Requests international standards to be set up as per technical regulations.
Article 2.2 and 2.4 (relevance to TBT)	Requests members to use international standards for legitimate objectives that include protection to human health or safety, animal or plant life or health, or the environment.
Articles 2.9, 2.11, 5.6, 5.8 and 10	Seek to enhance transparency in the establishment of the standards.
Article 3.1 (Relevance to Agreement on Subsidies and Countervailing measures	Prohibits subsidies if they rely on export performance, or are contingent on use of domestic rather than imported goods.
Article 8.2 (c) (relevance to ASCM)	Allows for assistance to existing facilities to promote adaptation to new environmental requirement in specific circumstances; however, this provision is time limited and not renewed in 1999.
Article 27 (2) (Relevance to TRIPs)	Requires that patents be available for all inventions, but adds that members can prevent patents to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
Article 27. 3 (b)	Allow members to exclude from patenting "plant, animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes. However, members are to provide for the protection of plant varieties either by patents or by an effective *sui generis* system or a combination thereof".
Article 66.2	Calls for developed country partners to encourage transfer of technology to developing countries.

natural substances, especially those based on either process or product. Biotechnological interventions receive much attention since many patents based on biotechnology fall within the two categories (products and processes). While Europe and North America do not differentiate these categories, several developing countries prefer otherwise. The present amendment to the Indian Patent Act recognizes the fine difference between these categories when it comes to biotechnological intervention, offering product patents.

Regarding patenting of plants, several countries have already adopted the UPOV systems in Asia while some countries like India have opted to develop a *sui generic* system to suit the national needs and interests. Sahai and Kumar (2003) offer a comprehensive comparison of the plant variety protection scenario in Asia.

CBD, Biosafety Protocol and WTO: Linkages and Conflicts

At the WTO ministerial conference in Doha, the relationship between WTO rules and MEAs was identified as a key issue for the ninth round of multilateral trade negotiations at the 5th WTO Ministerial Conference. Identification of specific trade obligations (STOs) will be the starting point of the negotiations of the WTO-MEAs' relationship. WTO Members have begun substantive discussions to examine STOs under certain MEAs. However, STOs under MEAs can cover a wide spectrum of possibilities, ranging from trade bans to notification procedures or labelling requirements. For example, Switzerland identified two categories of measures that arose from trade obligations. The first category includes mandatory trade measures explicitly provided for under the MEAs. This is the case of the Protocol since it requires advanced informed agreement (AIA) procedure for the first shipment of LMOs; the second category, non-mandatory measures, which are not explicitly provided for under MEAs, but are appropriate and necessary to achieve a MEAs' objectives. Under the Protocol issues of labelling will come under discussion through this category.

It must be noted that the Protocol is one of the elements of an MEA that has been negotiated by the countries with different backgrounds and interests in biotechnology and the final outcome is a package reflecting the internal balance of rights and obligations. Hence, identifying and clarifying what constitutes the STOs will be helpful to increase the weight of the Protocol on the negotiations on environment and trade.[2] A detailed analysis of the text of the Protocol reveals the following aspects as relevant to trade related measures and LMOs.

(1) Advance informed agreement (AIA) procedure (Article 8-10). The procedure is the Protocol's central mechanism regulating the decision-making process for the first shipment of LMOs intended for introduction into the environment of the Party of import. The AIA procedure starts with the notification of the proposed movement (transboundary) of the LMO to the Party of import. This notification needs to contain certain information relating to the exporter, the LMO and its intended use, as well as other information. The next step is that, within 90 and 270 days of receiving the notification, the Party of import must acknowledge receipt and inform its decision to the notifier and the Biosafety Clearing-House (established by the CBD), respectively. According to the AIA procedure, four possible decisions from the Party of import may be made: approve the import of the LMO, with or without conditions; prohibit the import of the LMO; request additional information; or inform the notifier that the import decision will be taken within a further defined period of time.

As per the AIA procedure, the elements which influence the decision of import of LMOs include the accuracy of information provided by the exporter (Article 8(1)), the existing scientific evidence available for risk assessment (Article 10(1)), the efficiency of decision-making of the importing Party (Article 9(2) and 10(2)), and the flexibility of applying the precautionary approach (Article 10(6) and 11(8)). In effect, inaccurate information from the exporter and inefficient decision-making processes of the importing Party will cause the exporter to lose the good chance to occupy the international market of LMOs, while discretion on the risk associated with a LMO, in the case of insufficient scientific knowledge and evidence may lead to a refusal to the import of the LMO.[3]

(2) Precautionary approach (Article 1, 10 and 11). The precautionary principle has increasingly been reflected in many international treaties and national laws on environment and natural conservation since 1970s. However, two different formulations of precautionary principles are in use, ranging from soft to strong formulations (Box 1).

While examining the Protocol, it is easy to understand that the precautionary principle under the Protocol is a soft formulation. For example, the preamble under the Protocol reaffirms the precautionary approach contained in Principle 15 of the Rio Declaration and Article 1

Box 1: Two formulations of precautionary principle

The formulation contained in Principle 15 of the Rio Declaration on Environment and Development is relatively soft, where it says "to protect the environment, the precautionary approach shall be widely applied by states according to capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not used as a reason for postponing cost effective measures to prevent environmental degradation". That is, regulators can take cost-effective steps to prevent serious or irreversible harm even when there is no certainty that such harm will occur.

A strong formulation is set out in the 1990 Third Ministerial Declaration on the North Sea, which requires governments to "apply the precautionary principle, that is to take action to avoid potentially damaging impacts of (toxic) substances... even where there is no scientific evidence to prove a causal link between emissions and effects". The formulation requires governments to take action without considering offsetting factors and without scientific evidence of harm.

Source: UNDP-HDR, 2001.

states that the objective of the Protocol is to be pursued "in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration".

In addition, the Protocol also contains some strong provisions for actions in circumstances of scientific uncertainty. For instance, the commitment to the precautionary approach is further operationalised in Article 10, which governs the AIA procedure by which the Party decides on the import of LMOs. Article 10 (6) states that "lack of scientific certainty... shall not prevent a Party from taking a decision, as appropriate, with regard to the import of the LMO in question..." A similar clause is contained in Article 11, which covers the special case of the LMOs intended for direct use as food, feed or for processing (LMO-FFPs). This gives the precautionary principle a significant role in the decision to restrict or prohibit the import of LMOs.

(3) Risk assessment (Article 15). Risk Assessment under the Protocol is a scientific tool for the implementation of the AIA procedure. As per the Protocol, the importing Party's decision must be based on a careful assessment of risk(s) that must be undertaken in a scientifically sound manner, taking into account recognized risk assessment techniques. Such risk assessment shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence as well as shall be carried out on the case-by-case basis. In addition, the Party of import has a right to require the exporter to carry out the risk assessment and its cost shall be borne by the notifier.

(4) Handling, transport, packaging or labelling requirements (Article 18). Article 18 of the Protocol requires all Parties, prior to export, to identify through accompanying documentation any LMO-FFPs that "may contain" LMOs, and identify any LMOs for intentional introduction into the environment (LMO-IIEs) or LMOs destined for contained use (LMO-CTUs). The Protocol also authorizes both exporting and importing Parties to take measures to ensure this identification takes place. The labelling of LMO-FFPs may lead to better matching of individual consumer preference, but when preferences differ, some consumers shall necessarily be unsatisfied by the social outcome. For example, if consumers perceive genetically modified (GM) foods as posing potential health and environmental risk, then presumably, risk-averse consumers would choose to consume more conventional foods, while the risk-neutral would choose either GM or conventional foods. On the other hand, the labelling of the products derived from modern biotechnology will also cause an increase in the cost of their production. In addition, Article 18 states that handling, transport, and packaging requirements for GM products shall be considered for elaboration in the future meeting of the Party to the Protocol. However, the impacts of this future outcome on LMO trade needs to be further identified.

While many policy makers and environmentalists weigh the benefits and costs of labelling, they are not always clear on whether labelling can be a useful policy tool.

This might lead to conflicts under the WTO regime when labelling becomes mandatory. This is why the Protocol discussion is on going about labelling and the *'may contain'* clause is becoming contentious. One way out of this impasse will be to make labelling voluntary but based on discussion between importers and exporters. However, if the importers require further information, the exporters could have the choice to provide the contents of the labels supplemented by the labels provided by the importing countries.

(5) Socio-economic considerations (Article 26). The Party, in reaching a decision on an import, may take into account the socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biodiversity, especially with regard to the value of biodiversity to indigenous and local communities. Article 26 identifies the types of socio-economic considerations and require that such considerations be taken into account consistent with a Party's other international obligations. Finally, it encourages Parties to cooperate on research and information exchange on the potential socio-economic impacts of LMOs.

Concerns and Conflicts between the Protocol and WTO Rules

Relevance of the Protocol with the WTO Rules

Article I of the GATT requires any trade advantage conferred by one country on another to be extended to all WTO members (Most-Favoured-Nation Clause). Article III prohibits discriminatory treatment between "like" or competing domestic and imported products (National Treatment Clause). Article XI forbids any quantitative restrictions other than duties, taxes or other charges. Article XX contains a general exceptions' clause. The relevant parts of Article XX states that "nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: (b) necessary to protect human, animal or plant life or health; (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption;..."

The Technical Barriers to Trade (TBT) and the Sanitary and Phytosanitary Standards (SPS) Agreements were adopted to "further the objectives" and to "elaborate rules for the application of the provisions" of the GATT. The TBT and the SPS both are exclusive from each other. If a trade-related measure does not fall within the scope of the SPS Agreement, the TBT Agreement can cover it. The TBT Agreement applies to all measures affecting the trade in any products that are technical regulations or technical standards, as long as those measures do not fall under the SPS Agreement. The most specific of the three Agreements is the SPS Agreement. This Agreement, in simplest terms, governs all measures that may directly or indirectly affect international trade in any product. Unlike the SPS Agreement, the TBT Agreement does not expressly require a Member to analyze its regulation on the basis of a risk.

The scope of the Protocol implies that its implementation has implications for following the WTO rules. For example, the AIA procedures for the import of LMOs are likely to fall under the SPS Agreement, while labelling required under Article 18 of the Protocol will likely fall under the TBT Agreement. The GATT applies to all measures affecting any product in international trade, including LMOs.

Issues between the Protocol and the WTO Rules

Both the SPS and the TBT Agreements promote the use of science and risk assessment as a means for justifying trade-related measures. The Protocol's risk assessment procedures were designed along similar lines, viz. scientific evidence. In analysis of the texts of the Protocol and the three WTO rules, the following issues emerge that both the Protocol and WTO rules:

(1) recognize the impact of international trade activities on the environment and biodiversity in which species are basic components;
(2) realize the importance and necessity to ensure the safety for human, animal or plant life and health as well as environment;
(3) recognize the possibility of risks arising from of the transboundary movement of the products which contain harmful living organisms, including LMOs;
(4) recognize that it is necessary to take appropriate measures to regulate the transboundary movement of the products which contain harmful living organisms, including LMOs;
(5) recognize that risk assessment is rather critical to take appropriate measures to regulate the transboundary movement of the products which contain harmful living organisms, including LMOs and emphasized that the risk assessment must be based on scientific information and data, as well as should take into account internationally recognized techniques and methodology (Table3);
(6) consider that application of the precautionary principle to the decision in the case of insufficient scientific knowledge and evidence;

Potential Conflicts between the Protocol and the WTO Rules

Even though the WTO Rules and the Protocol took into consideration respective needs of trade and environment safety, the distinction of their fundamental objectives may lead to the potential conflicts in regulatory measures taken to ensure the achieving of their respective objectives. From the drafting and negotiation of the Protocol through

Table3: Similarities in Risk Assessment Elements under the Protocol and SPS

Risk assessment under the Protocol	Risk assessment under the SPS
In a scientific sound and transparent manner (Article 15 and Annex III)	Take into account available scientific evidence (Article 5(2))
Taking into account expert advice of, and guidelines developed by, relevant international organizations (Annex III)	Taking into account risk assessment techniques developed by the relevant international organizations (Article 5(1))
Based on the available scientific evidence (Article 15(1))	Take into account available scientific evidence (Article 5(2))

its finalization, among the most contentious subjects are the application of precautionary approach in the conditions that scientific evidence is insufficient and the socio-economic considerations in the decision of importing LMOs. Following are the analyses of some potential conflicts between the Protocol and the three WTO rules.[4]

(1) From the risk assessment perspective, the LMOs considered under the Protocol are equivalent to the organisms that are regarded as pests, diseases, disease carrying or disease causing under the SPS. This means if substantive equivalence exists between the both, there is a possibility to undertake risk assessment in same or similar manner for the products under the Protocol and the SPS. Otherwise, it may be scientifically sound and reasonable to undertake risk assessment in line with the nature of the organism.

(2) The specified risks that LMOs may pose to biodiversity and to human health are not identified in the Protocol, while three categories of risks have clearly been identified in Annex A of the SPS. Hence, it is not possible to determine in advance, which WTO Agreement (the SPS or the TBT) will apply to trade-related measures taken under the Protocol.

(3) There are clear differences in the details of carrying out risk assessment for a LMO (Table 4). This may lead to a different risk estimate made on the basis of the assessment. As shown in Table 4, with regard to a certain biotechnology product, the details needed to be considered for risk assessment under the Protocol and the SPS are very different. Cosbey and Burgiel (2000) identified several differences in the approach to risk assessment between Article 5.7 of the SPS and the relevant provisions of the Protocol. First, the SPS does not specify exactly what a risk assessment is, but the Protocol elaborates this in detail in Annex

Table 4: Different Elements to be Considered in the Risk Assessment

The risk assessment under the Protocol	The risk assessment under the SPS
Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk (Annex III)	In the case of insufficient relevant scientific evidence, a Member may provisionally adopt sanitary or phytosanitary measures which will be subject to following points:(i) they must be adopted on the basis of available pertinent information;(ii) the Member must seek to obtain the additional information necessary for a more objective assessment of the risk; and(iii) the Member must review the measure within a reasonable period of time.(Article 5(7))
Details needed to be considered for the LMO in risk assessment (Article 15 and Annex III): - Recipient organisms or parental organisms - Donor organism(s) - Vector - Insert and/or characteristics of modification - Characteristics of LMOs - Detection and identification of LMOs - Information relating to the intended use - Receiving environment	Details needed to be considered for the product in risk assessment (Article 5(2)): - Processes and production methods - Relevant inspection, sampling and testing methods - Prevalence of specific diseases or pests - Existence of pest- or disease-free areas; - Quarantine or other treatment. - Relevant ecological and environmental conditions
The steps to carry out risk assessment (Annex III)	Not specified
The cost of risk assessment may be borne by the exporter (Article15.3)	Not specified

III. Secondly, the SPS does not mention risk management, but merely risk assessment. The Article 15 and 16 of the Protocol mentions both exercises, respectively, defining the latter as the gathering of the data, and the former as the building of a regulatory regime based on that data. It gives detailed guidance as to the establishment of the regime, e.g. asking parties to try to ensure that any LMO should undergo an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use.[5]

(4) The application of the precautionary approach under the Protocol and the SPS is different. Under Article 10 (6) of the Protocol, lack of scientific certainty shall not prevent a Party from taking a decision, as appropriate, with regard to the import of the LMO in order to avoid the adverse effect of the LMO on conservation and sustainable use of

biodiversity, taking into account risks to human health. Because the Protocol does not give a limit to the application of the precautionary approach, its application is very flexible based on the different purposes. However, the SPS clearly indicates that the level of sanitary or phytosanitary protection shall be appropriate (Article 3.3). The measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility (Article 5.4). To sum up, the significance of the precautionary provisions in the Protocol is that they fill in some of the gaps in the SPS. Indeed some precautionary provisions (Article 10(6) and 11(8)) of the Protocol are even stronger than the general expression of the precautionary principles in Principle 15 of the Rio Declaration and obviously geared towards an area in which there is a great deal of uncertainty and concern.

(5) The socio-economic considerations applied to a decision of import in regard to a LMO aroused debates during the negotiation of the BSP. Pursuant to Article 26 of the Protocol, in reaching an import decision of a LMO, the Party of import shall consider: the impact of LMOs on the conservation and sustainable use of biodiversity, and the value of biodiversity to indigenous and local communities. Hence, the scope of socio-economic considerations under the Protocol is wide, while SPS puts strict limits on the economic considerations: the potential damage in terms of loss of production or sales in the event of the entry, the establishment or spread of a pest or disease, the costs of control or eradication in the territory of the importing Member, and the relative cost-effectiveness of alternative approaches to limiting risks.

(6) The mandatory labelling of LMO-FFPs under the Protocol may be in conflict with the WTO rules. Firstly, under the Protocol, each party takes measure to require that documentation accompanying LMO-FFPs clearly identifies that they "may contain" LMOs. This involves very costly identity preservation mechanisms all along the supply chain from input suppliers and farmers to retailers. As a result, this will also put those wishing to sell non-LMO products at a considerable commercial disadvantage. Secondly, the TBT and the SPS in the WTO cover the issue of labelling, but the labelling must have a scientific basis and a risk assessment must be undertaken before labelling. However, the Protocol mandates a risk assessment without making clear which part the precautionary principle will play a role in the risk assessment

process. Further, the kind of risk assessment to be carried out for the purpose of labelling is also not defined under the protocol.

Conclusions

The development discussions related to technology transfer and cooperation are taking a centre stage. The Millennium Development Goal (MDG) 8 calls for global partnership to achieving sustainable development. Focus on biotechnology and IPRs are important since there is increasing interest in assessing their role in improving economic and social well-being besides contributing to better environmental management. However, the complexities of processes and impacts of international processes such as CBD, WTO and the related (Biosafety Protocol and TRIPs) are yet to be understood by many countries. In addition, countries are yet to assess the capacity needs to deal with the issues at national levels making cooperation a one-sided debate. It is important that assessment of national implications and obligations of CBD and WTO is carried out thoroughly.

Like development debates that are based on social, economic and environmental issues, technical and technological issues should also be based on the above issues. Unfortunately, the social elements are often missing in the debates related to biotechnology and IPRs making the issues complex and questioned by common people.

With increasing moves towards south-south cooperation, Asia is very well placed to take forward the technology transfer and cooperation agenda. The following might help the process:

1. Establishment of a regional clearing house on information and experiences related to biotechnology and IPRs
2. Creation of a regional network of experts on these issues
3. Further strengthening of initiatives such as the Asian Cooperation Mechanism
4. Joint efforts between countries to exchange expertise and share lessons learnt
5. Stronger regional and sub-regional (SAARC and ASEAN) 'voices' at international debates and negotiations – based on proper preparatory processes and needs assessments, and
6. Development of human and institutional capacities to deal with the issues.

While the issues on hand are no doubt complex, complexity should not be an excuse for inaction.

Endnotes

[1] Crucible Group 1994; Cameron and Makuch 1995

[2] Wang, 2003

[3] Mackenzie, 2003

[4] Mackenzie et.al. 2003

[5] Mackenzie et.al. 2003

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Challenges of Agro-Biotechnologies, Intellectual Property Rights and Globalization

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The new economic environment of liberalized policies and increasing 'globalization' has shaped the character of S&T and its organizational structure. This phenomenon has not only offered many promises but has also raised a number of socioeconomic, ethical and political issues. Information technologies have not only revolutionized industrial production and trade but have also made the organizational walls disappear and boosted international integration. Biotechnologies have opened new doors for treating genetically linked diseases, increasing agricultural productivity, nutritive qualities of food crops and for utilizing vast bio-resources of the South. Moreover, increasing environmental degradation, population pressures, consumption levels against the backdrop of depleting resources, glaring socioeconomic disparities and a relative ineffectiveness of modern S&T to solve many problems have raised many questions.

S&T policies have focused on different issues at different periods in the last fifty years from S&T infrastructure to military needs and from socioeconomic issues to innovation strategies. However, at present

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juncture, S&T policies of most of the countries might not be able to ignore and address the issues arising out of 'globalization' and the emerging technologies. As these technologies have evolved along the same period as with the introduction of liberalized regimes, globalization, international environmental movement, new international patent regime and the controversies surrounding the socioeconomic impact of the same, it is pertinent to study these technologies and policies. The present paper is an attempt to analyze the challenges posed by agro-biotechnologies, intellectual property rights (IPR) and globalization. Along with the rapid changes in the international system, the last two decades of the twentieth century have witnessed emergence of new technologies.

Globalization

Though globalization and liberalization process assumes free flow of technology and capital, it has belied expectations with varied regional and sectoral impact. There has been an increasing inflow of foreign direct investment (FDI) and technology from the developed to the developing countries with the introduction of liberalization. However, only a few countries have been able to attract and benefit from it, sectoral variations notwithstanding. As far as FDI in biotechnology[1] in India is concerned, a meager amount of a total of Rs. 1478 million (US $ 31 million) for 26 cases during 1999-2002 was invested. Moreover, declining official development assistance especially in the field of S&T from bilateral as well as multilateral sources[2] in the last two decades or so to the developing world has heightened the importance of multinational corporations (MNC) and FDI.

Liberalization of trade in the East Asian countries and the Latin American countries has yielded different results. Some studies[3] provide evidence that appear to confirm that the two regions in their process of trade liberalization followed a different path. On the one hand, the evidence for the four little tigers in East Asia consistently supported the hypothesis of a reduction of the wage differential between base-educated and skilled workers in the period succeeding the process of trade liberalization; on the other hand, in most of the Latin American countries an increase in inequality was clearly observed in the period following the effort to liberalize trade.

Though liberalization has brought productivity, efficiency and growth into focus, questions are being raised as to whether these policies will ameliorate or exacerbate existing socioeconomic disparities and aggravate the deprivation of the poor and exclude them totally from the rapid growth and development process.[4] It is also observed that national systems of innovations are under increasing strain[5] not only in the developing countries but also in the industrialized countries due to liberalization, competition, increasing range of technologies and uneven technological development.

Poverty Alleviation

Despite rapid technological advances, the issue of poverty alleviation still plagues S&T policies of most of the developing countries. Historically, there is evidence to suggest that technical advances have improved living standards and life expectancy. At the same time, there are examples of increasing inequality and bridging of inequality in different regions. Thus questions are being raised whether the issues of inequality, poverty and hunger should be treated separately. In the last several decades, in some countries, the incidence of poverty [6] has fallen. People living below the poverty line in the developing countries have generally declined during the last decade (1990-2001).[7] However, in Sub-Saharan Africa, which had the highest proportion of poor, there was an increase from 45 to 46 per cent. The South-Asian region that had the second highest proportion of poor people (41 per cent) has shown a decline to 31 per cent. These countries include even large countries like China and India. However, the absolute number of poor people in the world has continued to rise and inequalities between the richest and poorest countries have risen.[8] Globally, nutrition has improved in recent decades, but malnutrition—including deficiencies in micronutrients—is still widespread. Policies that reduce the negative and enhance the positive effects of globalization on nutrition and groups most at risk will be needed, at both the international and national levels. Enabling developing countries to import food at adequate and stable prices still remains a daunting task. Three-fourths of the world's poor live in rural areas and depend—directly and indirectly—on agriculture. In about 25 per cent of developing countries more than two-thirds of total exports are agricultural commodities.

In the preceding context, what role can the emerging technologies play? Could biotechnologies solve the problem of hunger and rural poverty? Some case studies[9] suggest that a strategy of dovetailing biotechnologies with the economic priorities, resource endowment and

S&T infrastructure of a country can bring about positive results and economic benefits but sometimes economic disasters in terms of labour displacement, loss of revenues and export earnings or wastage of resources. Hence, it is crucial to understand the changing structure of agricultural research and technology and features of the agro-biotechnology industry.

Features of Biotechnology Industry

According to an estimate, the global biotechnology industry has expanded to the tune of about $ 250 billion. It is comprised of 4,284 companies (622 public; 3,662 private) in 25 nations. The 622 public companies generated revenues of $35 billion, spent $16 billion in R&D and employed more than 188,000 people in 2001. As part of the global biotechnology industry, Indian industry is still a fraction.

Indian sales in biotechnology products are estimated at $ 3 billion in 2002. By the year 2005, it is expected that India can grow exponentially and improve its share in the global marketplace to about 5 per cent.

Globalization has accelerated the process of exposing the developing countries to the IPR preferences of the inventors of the technologically developed countries. The new IPR has particular implications for biotechnology (patenting activity in the biotechnology sector has registered roughly a ten-fold increase between 1985-2000). It is likely that the patenting of basic DNA sequencing could hamper rather than foster the downstream development of useful biotechnology products. The countries that lag behind in appropriating patents on DNA sequences will find themselves vulnerable. Access to genomic database and search software at reasonable costs are also crucial issues for the developing countries. Another important issue is the collaborative innovations and sharing the benefits of the same between the international biotechnology companies and the farmers in the developing countries. The conflict between breeders' rights, farmers' privilege and biotechnology patents and genomics database will have to be resolved amicably in order to have access to the germplasm and bio-resources of the developing countries.

It is pointed out by some scholars that the green revolution technologies with the productivity gains that they have brought about have made a major impact on poverty reduction in the last five decades. However, the benefits of these technologies have leveled off. For example, the yield growth has slowed down (from an average of 2.9 per cent per year for cereals in 1967-82 to 1.8 per cent in 1982-94). This may be due to depressed crop prices, increased input demands and resultant increase in fertilizer and pesticide prices and increasing water scarcities. Will this reduced yield growth of the existing technologies meet the projected demand? Are the emerging technologies answers to these problems in the prevailing socioeconomic and international system? Will the emerging technologies increase the bio-safety risk to the poor or provide such benefits as increased productivity, reduced risks in terms of pests and drought-induced losses, improved storability, enhance health standards by nutritional improvement (with micronutrients like Vitamin A, iron, zinc, etc.), reduced exposures to agrochemicals and development of edible vaccines?

Some of the answers to these questions can be found by analyzing the socioeconomic impact of the biotechnology industry that has, in the last two decades, expanded rapidly and widely. The estimated global area under transgenic crops[10] has increased from 1.7 million hectares in 1996 to 44.2 million hectares or 109.2 million acres in 2000 registering a twenty-five fold increase. Hence, it is doubtful whether it will have any serious impact on food security and poverty reduction. Global R&D expenditure in the private and public sectors is $4.4 billion with over 95 per cent of the total in the industrial countries, led by the US. China is the leading investor in R&D on crop biotechnology in the developing countries, followed by India.

Agro-biotechnology Sector in India

The Indian agro-biotechnology sector is still in an incipient stage[11] and any evaluation at this stage would be premature. Nonetheless, some observations could be made given the rapid growth of the sector in recent years and conscious interventions made by the government.

The only approved crop so far is cotton. India is currently the world's third largest cotton producer behind (8.9 million hectares) China (4.56 million) and the United States (5.37 million). Although India has more land under cotton cultivation than any other country in the world, it yields only 298 kg (655 pounds) per hectare, compared to the global average of about 650 kg (1,430 pounds). It is expected that India would dominate the global market in the use of GM cotton. However, the yield results have provided a mixed picture of success, failure and partial success. Gujarat, the state that pioneered hybrid seeds in the world, has seen a rapid diffusion of this technology. At the same time, there are reports that most of these hybrid seeds are disappearing along with traditional varieties thereby posing a threat to biodiversity.

It is also reported that the socioeconomic consequences are not positive either in some cases. Some of the seed companies including the MNCs are employing female children as bonded labour[12] on some hybrid cottonseed farms in India. Moreover, attempts are being made by some companies to release new cotton hybrids using CMS (Cytoplasmic genetic Male Sterility) technology, which reduces the requirement of labour in production of seeds by half. No GM food crops have been introduced so far. If GM food crops with enhanced nutritive qualities and reduced expenditure on fertilizer and pesticides can be developed and cultivated, it can result into considerable positive impact on poverty alleviation. However, as revealed by the efforts made so far, the major emphasis is either on pest resistance or abiotic stress. These efforts might reduce some financial losses. However, so far due weightage is not provided to enhancement to nutritive qualities in the GM crops.

To accelerate the growth in biotechnology sector a separate Department of Biotechnology (DBT) was set up under the Ministry of Science and Technology in 1986. In the year 2001, the DBT came out with a document setting out a ten-year vision of India's biotechnology. Its vision statement is: "Attaining new heights in biotechnology research, shaping biotechnology into a premier precision tool of the future for creation of wealth and ensuring social justice specially for the welfare of the poor."

The vision document *inter alia* states that transgenics of rice, brassica, mungbean, pigeonpea, and some vegetables like potato, tomato, cabbage, and cauliflower and cotton would complete field

Transgenic wheat with more protein content and better quality and also higher lysine content and market assisted breeding programme is expected to be introduced in farmers field by 2003-2005. Both laboratory research and field trials are already being conducted on various genetically modified crops that include rice[13], tobacco, potato, tomato, Brassica, mustard/rapeseed, and cotton (see Table1).

As revealed in Table 1, the major emphasis is either on pest resistance or abiotic stress. These efforts might reduce some financial losses. However, so far due weightage is yet to be provided to enhancement of the nutritive qualities in the GM crops.

Edible vaccines, particularly for cholera, rabies and hepatitis B, work on which is already in progress, would be ready for clinical trials by 2003-2004, with an expression gene in tomato, cabbage and banana.

Other efforts that are being made include transgenic bio-fertilizers and bio-pesticides. Bio-prospecting, molecular taxonomy and documentation of the economically and ecologically important hot spots of biodiversity in the country, are also underway. Plant Tissue Culture is also being taken up in the areas that need massive afforestation and wasteland recovery.

India's Agro-biodiversity

India has over 45,000 wild species of plants and 77,000 wild species of animals recorded. These together comprise about 6.5 per cent of the world's known wildlife. India's biological heritage is impressive not only in its sheer diversity, but also in its uniqueness. India is one of the 12 mega-biodiversity areas of the world. India's record in agro-biodiversity is equally impressive (Table 2). There are 167 crop species and wild relatives.

India is considered to be the centre of origin of 30,000-50,000 varieties of rice, pigeon-pea, mango, turmeric, ginger, sugarcane, gooseberries, etc. and ranks seventh in terms of contribution to world agriculture. Similarly, significant is the indigenous livestock diversity with 27 breeds of cattle, 40 of sheep and 22 of goats.

It has been estimated that at least 10 per cent of India's recorded wild flora, and possibly a larger fraction of its wild fauna, are on the threatened list, many of them on the verge of extinction. This is not surprising considering the fact that in the last few decades, India has lost at least 50 per cent of its forests, polluted over 70 per cent of its water-bodies, built or cultivated over much of its grasslands and degraded most of its coasts. In addition, hunting, overexploitation, poisoning by pesticides, excessive botanical and zoological collection, displacements by exotics, and a host of other activities have taken a heavy toll of biodiversity.

Conflicts between TRIPs, Agriculture, Food Security and Biodiversity

Agriculture is the mainstay for most of the developing countries compared to other sectors. For the majority of the population in most of these countries, agriculture has played crucial role in poverty

Table No. 1: Status of GM Crops in Inida

Crop	Trait	Status Lab	 Field trials	Institution(s) Involved
Brassica	Tolerance to moisture stress (annexin gene)	Yes	Yes	Unavailable
Brinjal	Resistance to pests (Bt gene)	Yes	Unavailable	Unavailable
Cabbage	Resistance to insect pests (Bt gene)	Yes	Unavailable	Unavailable
Cauliflower	Pollination control and hybrid development (barnase/barstar genes)	Yes	Unavailable	Unavailable
Cauliflower	Resistance to insect pests (Bt gene)	Yes	Unavailable	Unavailable
Cotton	Resistance to lepitopteran insect pests (Bt gene)	Yes	Yes	Unavailable
Mustard/Rapeseed	Pollination control for hybrid development (barnase/barstar genes)	Yes	Yes	Unavailable
Potato	Resistance to potato tuber moth (Bt gene)	Yes	Unavailable	Unavailable
Potato	Tolerance to moisture stress (osmotin gene)	Yes	Yes	Unavailable
Potato	Improved nutritional quality (Ama-1 gene)	Yes	Unavailable	Unavailable
Rice	Resistance to yellow stem borer (Bt)	Yes	Yes	Unavailable
Rice	Resistance against lepidopteran, coleopteran in pests (snowdrop lectin gene)	Yes	Yes	Unavailable
Rice	Resistance against abiotic stresses (P5cs gene)	Yes	Yes	Unavailable
Rice	Resistance to sheath blight disease (chitinase gene)	Yes	Unavailable	Unavailable
Tobacco	Resistance to tobacco caterpillar	Yes	Yes	Unavailable
Tomato	Delayed ripening (ACC synthase gene)	Yes	Unavailable	Unavailable
Tomato	Resistance to fruit borer (Bt gene)	Yes	Yes	Unavailable

Approved crops

Crop	Trait	Type of Approval Food	 Feed	Environment
Cotton	Resistance to lepidopteran insect pests (Bt gene)	No	No	Yes

Table 2: India's Agro-Biodiversity

Crop	No. of wild relatives
Millets	51
Fruits	104
Spices and condiments	27
Vegetables and pulses	55
Fibre crops	24
Oil seeds, tea, coffee, Tobacco and sugarcane	12
Medicinal plants	3000

Source: National Action Plan for Biodiversity. Ministry of Environment and Forests, Government of India, New Delhi, 1997.

reduction, employment generation, food security and nutrition. However, the expenditure of developing countries on agricultural R&D (mostly through public funding) does not reflect the significance of agriculture to their GNP except in a few countries. Historically in these countries, technical progress and diffusion have occurred through a process of on-farm experimentation, selection and adaptation of traditional landraces of crops and through an *in situ* method for conservation purpose.

Later, hybridisation programmes were launched for selecting desirable characteristics. Another feature that requires to be noted is that the majority of farmers in the developing countries are small farmers and they depend on dryland agriculture and that the assignment of IPRs to living things is of relatively recent[14] origin in these countries.

The Trade related Aspects of Intellectual Property Rights (TRIPs) Agreement has been extended to this sector (except plants, animals and biological processes but including microorganisms). Under this agreement, developing countries may choose an "effective *sui generis*" plant variety protection (PVP) system or accession to the UPOV treaty (Union International pour la Protection des Obtention Vegetables). This has raised number of issues for the developing countries in the context of technological and organizational change. With the adoption of the TRIPs Agreement, developing countries have been obliged to adopt protection of plant varieties, by patents or by other means, without any serious consideration being given as to whether such protection would be beneficial, both to producers and consumers, or its possible impact on food security or whether it is a suitable mechanism for promoting technologies required and if so whether these technologies would be accessible to poor farmers. It is being argued that the treaties that evolved in the western countries, with food surplus and agricultural research that is overwhelmingly privately financed may simply promote commercial crops. Another contentious issue is whether the provisions of the TRIPs Agreement will succeed in protecting biodiversity as mentioned in the Convention on Biodiversity (CBD) or the plant genetic resources as mentioned in the FAO Treaty. While the CBD asserts national sovereignty over genetic resources, there is nothing in TRIPs to provide support to these CBD objectives. The TRIPs is silent about the equitable 'benefit sharing' and 'prior informed consent' that are emphasized in the CBD.

Farmers have traditionally replanted, exchanged or sold seed from the previous years' crop with no advantage to breeders profits that they made through repeat sales. Patents or Plant Breeder's Rights (PBRs) normally impose restrictions on farmers' ability to sell grown seed (and in some cases to reuse it) and thus enhance the market for the breeder's seed. Even in the developed countries, reuse of seeds remains quite common although for many crops annual purchase is now the rule. In developing countries the majority of farmers reuse, exchange or sell informally and annual purchase of new seed is relatively rare in most countries. In respect of IP, the CBD states that access and transfer (of genetic resources) should be consistent with the "adequate and effective protection of intellectual property rights." Governments should put in place policies to ensure that, particularly for developing countries, access to genetic resources takes place on mutually agreed terms. It notes that patents and other IPRs may have an influence on implementation of the Convention, and governments should cooperate (subject to national and international law) in order to ensure that such rights are supportive of and do not run counter to the CBD's objectives. It is also being pointed out that since patenting based on the use of genetic resources is allowed under TRIPs (subject to meeting patentability criteria), this does not support the objectives of the CBD because the criteria for patentability do not include prior informed consent or mutually agreed terms for benefit sharing. Foreign companies may obtain private rights derived from national resources.

In the developing countries there are large differences in plant breeding capability, the proportion of farmers that use modern varieties and the value of the plant genetic resources available. Thus, the impact of intellectual property protection (IPP) will be different for different regions.[15] In addition to this, the structure of agricultural research and technologies is also changing.

Changing Structure of Agricultural Research and Technologies

Recently, significant changes have occurred in both the structure of agricultural research and technology.[16] In most of the developing countries agricultural research has been financed through public sector and has account for almost 97 per cent. A positive correlation has been observed between the levels of income of countries and the proportion of agricultural research in private sector. As the proportion of the same increased with the level of national income, and the in the countries with per capita income of about USD 2000 and above, the proportion of private sector contribution reached almost 25 per cent. Moreover, in developing countries, especially from Africa, one or two commercial crops are encouraged at the neglect of food crops. The national and international funding agencies have also contributed in strengthening research system tilted in favour of the same.

With the emergence of biotechnology, a technological possibility of introducing new genetic traits in plant has become reality. From economic point of view, the focus of agricultural research has shifted from public sector to private sector or to university system. Moreover, due to liberalisation policies, the national and international funding for agricultural research is also shrinking or stagnating. Thus, the share of private funding is likely increase resulting into greater influence of market forces guiding the direction of the same. The preceding tendencies and the new PVP system is expected to strengthen the existing situation.

Biodiversity and Conflicts in the International Treaties

The requirement for uniformity (and stability) in UPOV type systems excludes local varieties developed by farmers that are more heterogeneous genetically, and less stable. But it is these characteristics that make them more adaptable and suited to the agro-ecological environments in which the majority of poor farmers live. It would be open in principle for developing countries to devise systems that would offer protection for varieties that meet criteria suited to the circumstances and crops on which poor farmers depend. However, in reality such criteria may be difficult to devise and costly to operate. In such a situation, governments may not find such a system useful for their farming systems.

While proponents argue that by stimulating the production of new varieties, PVP actually increases biodiversity, others claim that the requirement for uniformity, and the certification of essentially similar varieties of crops, will add to uniformity of crops and loss of biodiversity. This concern certainly goes wider than PVP. Seed legislation in many countries imposes strict uniformity requirements, sometimes stricter than PVP legislation. Moreover, similar concerns have arisen in respect of greater uniformity arising from the success of Green Revolution varieties, leading to greater susceptibility to disease and loss of on-field biodiversity. As plant breeding becomes an increasingly private sector activity, new varieties are likely to displace traditional varieties on a large scale. Then, a crucial issue that will arise is of how genetic resources are to be conserved and maintained for possible future use, whether in fields (*in situ*) or in "gene banks" (*ex situ*).

There are considerable dangers to food security if the technologies are overpriced to the exclusion of small farmers, or there is no alternative source of new technologies, particularly from the public sector. Further, the increase in concentration, and the conflicting patent claims when both the public and private sectors have patented plant technologies, may have an inhibiting effect on research. In the private sector the response has been alliances or acquisitions, but a problem for the public sector is how to access the technologies they need to undertake research without infringing IP rights and, if they develop new technologies, the terms on which they may be made available.

It is the failure of the breeders' rights to address the problems of poor farmers that has led to the movement for farmers' rights. In 1989 the FAO agreed to recognise these concerns by incorporating Farmers' Rights "arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the centres of origin/ diversity". Finally in 2001, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) took shape.[17] The ITPGRFA recognises the contribution of farmers in conserving, improving and making available genetic resources, and that this contribution is the basis of Farmers' Rights. It does not limit in any form whatsoever rights that farmers may enjoy under national law to save, use, exchange and sell farm-saved seed. It also sets out the right to participate in decision making about, and to derive fair and equitable benefits from, the use of these resources. An essential feature of this treaty is that it will implement a

"Multilateral System" as opposed to the existing CBD "Bilateral System" of access, to a list of some of the most important food and fodder crops essential for food security and interdependence, for those countries that ratify the Treaty. It will ensure that benefits from the commercial use of the genetic resources of these crops are returned to farmers in developing countries, the original source of most of the resources. Will the "Material Transfer Agreement " (MTA) that has to be developed be equitable and protect crop genetic resources from privatization? In the recent past there were examples of privatization of germplasm deposited at the CGIAR genebank. However, the attempt of an MNC called Syngenta was foiled. Not just National Collections but also CGIAR genebanks could come under increasing pressure from MNCs to exchange the genetic resources in genebanks under public and CGIAR control. Genebank managers have no right or permission to sell these genetic resources. The genetic resources are given to them by farmers to scientists and other collectors in good faith that they will be held in trust for the benefit of humankind and that it will not be turned into private property.

So far about 80 per cent of the trials of transgenic crops have occurred in developed countries, where three quarters of the world's GM crops are grown. The breeding strategies of the multinationals have been naturally oriented to the needs of developed world markets, and the commercial sectors of middle-income developing countries (for example, Brazil, Argentina or China). The development of genetic traits such as herbicide tolerance has been determined principally by the search for commercial advantage, rather than characteristics like nutritive value and cheaper price that are relevant to developing countries.

Most of the evidence relating to the impact of patent or plant variety protection on research is from developed countries, and even that is quite sparse. Before IP protection was introduced, private sector breeding initiatives focused on hybrid varieties, particularly of maize in the US, because inherent in these varieties is an element of "technological protection". In the US a study from the 1980s suggested that there was no evidence that total R&D activity had increased as a result of the introduction of PVP, although it appeared to have had some impact on soya beans and wheat. The latter crops also accounted for the majority of PVP certificates issued. There was also evidence that PVP was used as a marketing strategy for product differentiation and that it had contributed to the large number of mergers that took place in the seed industry. But the evidence is inconclusive, in particular because of the difficulty in isolating the effect of protection from other ongoing changes. Even now research spending on hybrid crops as a share of sales continues to exceed that on non-hybrid crops, which are the principal object of PVP. A recent study found that PVP on wheat in the US had not only contributed to increased investment in private sector wheat breeding, but may also have done so in the public sector. Nor had it contributed to an increase in yields. But the share of wheat acreage sown to private varieties had increased markedly, reinforcing the suggestion that the main impact of PVP was as a marketing tool. A major study conducted in middle income developing countries, found little evidence of an increased range of plant material available to farmers or increased innovation as a result of PVP protection. Access to foreign genetic material had improved, but its use was sometimes subject to export restrictions. For many developing countries agricultural commodities are the main source of foreign exchange earnings. Generally speaking, commercial farmers and the seed industry were perceived as the principal beneficiaries. Poor farmers had not benefited directly from protection, but could potentially be adversely affected by restrictions on seed saving and exchange in the future.

In contrast, TRIPs only requires that there should be some form of IP protection for plant varieties, and does not define in any way the exceptions that may be provided to the rights of owners of protected varieties.

TRIPs Provisions

Many of the developing countries have realized the inadequacy of the existing IPP system to protect traditional knowledge. They were also successful in convincing the TRIPs Council that it should engage in further work on protecting TK. This was also highlighted in the Doha WTO Ministerial Declaration. A final consensus is yet to emerge on this issue as the Article 27.3 (b) is still under review.[18]

The reasons for this concerns gaining currency are several. The global market for traditional medicine is already worth US $75 billion a year and is growing steadily. In the developing countries about 80 per cent of the population depend on traditional medicines to help meet their healthcare needs. In addition, knowledge of the healing properties of plants has been the source of many modern medicines. Moreover, in the recent past, there were some allegations of what is referred to as "biopiracy" and many of the patents were rendered invalid. Some of the known examples are basmati rice, turmeric, neem and ayahuasca. In these cases patent protection was granted to inventions relating to traditional knowledge, which was already in the public domain for a very long period. In another example, a patent was granted on a cactus plant called Hoodia. Here, the issue was whether the local people known as the San, who had nurtured the traditional knowledge underpinning the invention, were entitled to receive a fair share of any benefits arising from commercialisation.

The concept of protection of TK introduced at the WTO meeting has evolved from several other international fora and actions taken in the recent past. In 1981, WIPO and UNESCO adopted a model law on folklore. In 1989 the concept of Farmers' Rights was introduced by the FAO into its International Undertaking on Plant Genetic Resources and in 1992 the CBD highlighted the need to promote and preserve traditional knowledge. In spite of these efforts, which have spanned two decades, final and universally acceptable solutions for the protection and promotion of traditional knowledge have not yet emerged.

The CBD also set out principles governing access to genetic resources and the knowledge associated with them, and the sharing of benefits arising from such access. This involves the relationship between the IP system and the access and benefit sharing principles of the CBD in the context of both knowledge, traditional or otherwise, and genetic resources. The higher share (USD 6 billion) of China in traditional medicine is attributed to combining modern S&T infrastructure with it and there are many countries like India, which have not made significant efforts in this direction and, therefore, are not able to increase their export share in the global TK markets. Thus, protection of TK would become important for the developing countries if investments on modernising TK were to be enhanced.

Concluding Observations

Agro-biotechnologies hold out the promise and many benefits for agriculture, agro-industry and thereby uplifting the rural poor. However, at the same time pose they many threats and risks. Biotechnology can contribute to future food security if it benefits sustainable small-farm agriculture in developing countries. Protection of intellectual property rights encourages private sector investment in agro-biotechnology, but in developing countries the needs of smallholder farmers and environmental conservation are unlikely to attract private funds. The ultimate success would also depend on conscious attempts by the government to evolve suitable policies and regulatory mechanism in order to derive the full benefits and avoid the risks. An effort to impose a stronger IPR system has raised many controversies surrounding the TRIPs agreement. There are many areas where the objectives of the national, bilateral, regional and international agencies are found to be in conflicts or in conflicting interpretation. In the final analysis, it seems that concerted efforts will be required on the part of the international community to link up agro-biotechnologies and IPRs with development objectives.

Endnotes

[1] Rao 2002.

[2] Desai 1997a.

[3] Morone 2000.

[4] Desai 2000.

[5] Patel & Paviit 1998.

[6] OECD 2002.

[7] Per cent of people living below $1.08 per day at 1993 PPP.

[8] World Bank 2000.

[9] Fransman 1991.

[10] Clive 2000.

[11] India's biotechnology industry currently comprise of 110 units in the health care products sector, 140 units in agriculture, and over 300 units in the industrial and other biotechnology products sector.

[12] Venkateswarlu, 2002.

[13] Scientists at the Directorate of Rice Research (DRR) in Hyderabad, India have undertaken a research that would produce genetically modified (GM) rice, which has resistance against six diseases. The durable, multiple-pest resistant rice is expected to be ready for the market by 2006. The six diseases mentioned contribute to significant financial losses since rice is being cultivated in about 45 million hectares in India.

[14] Vegetatively propagated plants were first made patentable in the US only in 1930. And the protection of plant varieties (or plant breeder's rights - PBRs), a new form of intellectual property, only became widespread in the second half of the 20th Century.

[15] Butler 2002.

[16] Desai 1997b.

[17] The USA and Japan were only two countries that abstained from this conference.

[18] Article 27.3(b) states regarding the patentable subject matter that plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective suigeneris system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

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Venkateswarlu, Davuluri. 2002. "Child Labour and Trans-National Seed Companies in Hybrid Cotton Seed Production in Andhra Pradesh". A Study commissioned by *India Committee of the Netherlands* [ICN].

World Bank. 2000. World Development Report. Oxford University Press. The ratio of per capita income between the richest and the poorest countries increased six-fold between 1870 and 1985.. Between 1970 and 1995, the average per capita GDP of the middle third has dropped from 12.5 to 11.4 per cent of the richest and that of the poorest third from 3.1 per cent to 1.9 per cent.

Bio News

This section puts together news about the recent and key developments related to intellectual property rights.

Monsanto wins key patent dispute regarding Dicot plant transformation

Monsanto Company announced that it has won the key patent battle regarding biotech-gene technology for the transformation of dicot plants, such as cotton. The decision by the U.S. Patent and Trademark Office (USPTO) that Monsanto's scientists were the first to invent this important discovery ends a 12-year patent interference dispute with the Max Planck Institute and other parties. The decision, issued by U.S. Patent and Trademark Office, recounts the basis for finding that Monsanto was the first company to invent *agrobacterium* transformation in dicot plants, which eventually gave farmers the choice to use biotech crops on their farms. The *agrobacterium* is one of the ways to insert beneficial characteristics into plants. Monsanto's Bollgard insect-protected cotton was developed using agrobacterium transformation for the formation of dicot crops. Monsanto Company is a leading global provider of technology-based solutions and agricultural products that improve farm productivity and food quality.

New patent regime may pose challenges to Indian farm sector

The Indian Parliament approved the Third Patents (Amendment) Bill 2005. This will meet the country's obligation to usher in new product patent regime under Trade Related Intellectual Property Rights (TRIPs) agreement of the WTO. The third amendment is slated to provide product patent regime in pharmaceuticals, food and chemicals, including agro-chemicals. The granting of patent rights over microorganisms, microbiological and non-biological processes for production of plants and animals are also covered under the third amendment.

All safeguards had been built in to the legislation to protect the interest of Indian pharmaceutical industry and prevent an inordinate rise in prices. The new legislation would not lead to an increase in the prices of essential drugs said the Indian Commerce Minister.

The Bill also stipulates that only a "new entity" involving "one or more inventive steps" will fit the criterion of patentable pharmaceutical substances. On compulsory licensing of life saving drugs and pre-grant opposition, the Bill has incorporated the necessary safeguards. Finally, the unnecessary restriction on the export of patented drugs manufactured generically in India under compulsory licence to less developed countries – such as the sale of African nations, at much lower prices, of antiretroviral to combat AIDS – have been removed. On the protection of traditional knowledge, plants were completely out of the purview of the legislation. Though India opted for *sui generis* system for protection of varieties and enacted a law for the purpose, it is likely that the transgenic seeds developed through human intervention may be covered under the new patent regime.

The Third Amendment to the Patent Act may, therefore, pose new challenges before the farm sector. In this context, the policy makers have a duty to ensure that several protections given to farmers like saving seeds for the next season under the Plant Varieties Protection & Farmers' Rights Act are not diluted. Similarly, the community rights ensured under the National Biodiversity Act should not be ignored. The challenge, therefore, before the government is to develop a holistic view of the entire intellectual property rights (IPR) regime in the country.

The TRIPs agreement has not defined microorganisms and microbiological processes. Here the question is whether the micro-organisms existing freely are patentable or their mere isolation in pure form are patentable or human intervention in establishing a level of novelty in the discovered micro-organism is needed for patenting. The United States Patent and Trademark Office (USPTO) verdict of the case *Diamond vs Chakraborty* in 1980 establishes that human intervention leading to a novelty in expression can be patented. It says: "respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not due to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter - a product of human ingenuity having a distinctive name, character and use... His discovery is not nature's handiwork, but his own..." The Government of India introduced many issues, including data protection and quality of patents, would need to be attended to even after the Third Patent (Amendment) Bill is passed by Parliament. There will be "immediate attention to data protection, particularly in the area of agrochemicals and agricultural biotechnology".

The farmer's bodies of India were opposed the recent patent ordinance, which seeks to introduce patent monopolies on seeds. With the proposed amendments to the Seeds Act, government policies attempt to modify the structure of regulated markets for agri produces. "The Patent Ordinance has proposed patent monopolies on seeds, genes and markers. This will lead to farmers' paying royalties to seed companies. Further, the proposed amendments to the Seeds Act, like compulsory registration, will prevent farmers from using farm-saved seeds", said the director of a Delhi based NGO.

The new Patents Act is going to change the global perception of India, which is now the preferred destination for pharmaceutical business and global opportunity. While the industry is set to undergo a major transformation with focus on discovery research, it could expect to gain revenue of at least $10 billion in the years to come, said Dr. William A. Haseltine, one of the leading experts in genomic and Chairman of the Scientific Advisory Board of Matrix Labs.

He also stated that Indian pharmaceutical market should not restrict its focus to regional markets and should aim at the global market by maintaining world-class standards. The contract research, contract manufacturing, venture capital and clinical trials are the areas in which the country can emerge as a major player in the global market. However, the country needs to take several measures to exploit these opportunities by strengthening the regulatory framework with respect to drug approvals and patents. At present, there are certain structural weaknesses in the Indian regulatory framework with regard to the drug approval process. The country also suffers from inadequate infrastructure in patent protection, said Dr. Haseltine.

Seed sowing and patent controversy

Monsanto sued Homan McFarling, a petitioner for saving seeds and replanting them. The seeds had been genetically modified by Monsanto to resist Roundup (R) herbicide and were patented. (U.S. Patents 5,633,435 and 5,352,605). At the Federal Circuit, McFarling argued that the Sales Agreement from Monsanto involved an unlawful misuse of Monsanto's patents by restricting use of "god-made" second-generation seeds. The Appellate Court disagreed. Because the first-generation seeds (sold by Monsanto) were nearly identical copies to the second-generation seeds, the Court found that the patent scope includes both generations. Thus, the Court rejected McFarling's appeal and held that the Sales Agreement did not impermissibly extend Monsanto's right. The Supreme Court has asked the Solicitor General to brief in this case expressing the views of the United States. It is expected that the Bush Administration, through the Solicitor General, will support Monsanto's position.

TRIPs council considers public health, biodiversity

The public health and biodiversity-related concerns emerged as major issues at the 2004 final meeting of the WTO Council for Trade-related Aspects of Intellectual Property Rights (TRIPs) on 1-2 December. At the meeting, Nigeria submitted a proposal (IP/C/W/437) on behalf of the African Group, which includes all African WTO Members for converting the waiver provided for in the decision on pharmaceutical patents into a formal amendment of the TRIPs agreement. Many developed countries criticized the Nigeria-led proposal, arguing that it sought to re-open the debate on the substance of the decision and would only complicate current discussions. The supporters of the proposal countered that the suggested text was only an attempt to simplify the complex nature of the waiver. In the session on biodiversity, traditional knowledge (TK) and folklore an attempt was made to move the substantive debate forward on the relationship between the TRIPs Agreement, biodiversity issues and TK with a new proposal (IP/C/W/438) submitted by Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela.

Open-source biology evolves

The scientific knowledge can be used for good or ill for the industrial application and other related activities. Scientists need to draw from the best data and innovations in their field to push research further. Much of the work and discovery, however, is patented, leaving many academic and non-profit researchers constrained. But an Australian organization advocating an open-source approach to biology hopes to free up biological data without violating intellectual property rights.

The knowledge like open-source software, open-source biology users own the patents to their creations, but cannot delay others from using the original shared information to develop similar products. The battle lies between biotechnology companies like multinational Monsanto, who can grant or deny the legal use of biological information, and independent organizations like The Biological Innovation for Open Society (BIOS) and Science Commons.

BIOS will soon launch an open-source platform that promises to free up rights to patented DNA sequences and the methods needed to manipulate biological material. Users must only follow BIOS' "rules of engagement, which are similar to those used by the open-source software community. There are technologies which need to innovate and then there are the innovations themselves," said Richard Jefferso, founder and director of BIOS in Canberra, Australia. But those can only happen when there is fair access to the technologies. Any improvements of the shared methods of BIOS, the Science Commons or other open-source communities must be made public, as well as any health hazards that are discovered. While free access to biological information will benefit those doing research, companies who have invested millions in patents, on the other hand, won't perform expensive groundbreaking research without a guarantee that their intellectual property rights would be upheld. "Patents attract investors, providing the resources necessary to bring the product to market," said Brigid Quinn, deputy director of public affairs with the U.S. patent office.

Survey shows IP laws favors developed countries

The development in intellectual property (IP) has raised concerns about IP's implications in food production and animal health, especially throughout the developing world. These same developments, however, are made more in developed countries, and little attention is given to developing nations. This was raised and explored in "Plants and Intellectual Property, an article written by Dr. Bonwoo Koo and colleagues, published in the Novemberl 19, 2004 issue of *Science*. With a survey conducted in national IP offices in 191 countries, researchers found that only 91 countries offered statutory IP protection, while another 29 countries had legislation under consideration. The majority of the 91 were high and upper middle-income countries; only 22 of 61 low-income countries had any statutory protection in place for plants. Surveys also showed that 31 per cent of the applications in high-income countries, 65 per cent in upper middle-income countries, 25 per cent in lower middle-income countries, and 38 per cent in low-income countries were lodged by foreigners.

Patent rights to agrobacterium technology

The Syngenta International AG (Basel, Switzerland) and Monsanto Company (St. Louis, Missouri) announced an agreement in which the companies cross-licence proprietary *Agrobacterium*-mediated transformation technology. The agreement resolved a patent interference proceeding in the United States Patent and Trademark Office (USPTO) involving transgenic broad leaf crops. The Monsanto-Syngenta deal also resolved a lawsuit that had been pending in the U.S. District Court for the District of Delaware. Syngenta had filed the case in 2002, alleging that Monsanto and Delta and Pine Land infringed U.S. Patent No. 6,051,757, which covers methods of transferring genes into dicotyledonous plants using *Agrobacterium* based vectors. On the day that the companies announced their new agreement, the Delaware district court dismissed the patent infringement case. Monsanto have the *Agrobacterium*-related patent rights. As the Monsanto's scientists had intentioned Agrobacterium transformation methods.

Access to research tools in biotechnology

The biotechnology industry's shifting ideology and the increasingly proprietary nature of research tools are hampering research efforts. Access to key data and research tools to deal with new scientific initiatives like plant biotechnology has become limited. Hence, there is a need for reforms to the current patent system to deal effectively with these problems. According to David Faye, winner of Borden Ladner Geravais LLP award in constitutional law. Canada's "the proliferation of patent rights could impede or effectively preclude use of the research tools". As such, some studies have shown that researchers are forced to circumvent the patent system, with one-third of private and public firms indicating that they use patented research tools without a licence. Again it focuses on the experimental use exception in patent law in the United States and the United Kingdom as a possible means to solve the problem. "If recent trends to narrow policy initiatives can be reversed or, at the very least, halted, the potential may exist for public policy initiatives to permit use of the exception in a manner which would ultimately benefit the intended sectors," Faye said.

Genetic Diversity and Patent Regime

After the UN Convention on Biological Resources at Bangkok, the issue of the new patent regime and how to regulate access to genetic resources comes out. The world's biggest developing countries Brazil, India and China along with others, want a global convention that would regulate patents on inventions developed from genetic resources. The concern is that developing countries, and their indigenous communities, are not securing the benefits when lucrative inventions are marketed. The issues to prevent the hijacking of genetic resources and to establish contract arrangements. There will be payment agreement for accessing the resources and right to use them. The world's biggest drug companies are the targets. Martin Khor, head of the Penang-based non-governmental organization and a long-time campaigner for curbs on intellectual property rights, said, "Farmers and indigenous peoples are outraged that plants they have developed are being hijacked by companies."

India, Brazil and other so-called "mega-diverse" countries have proposed something much more complicated. They want an international convention that controls patents. Even after a patent has been granted for an invention using genetic material, the country from which the material was sourced would have the right to determine how products based on a patented invention from it would be used. This would certainly stop bio prospecting because it would stop pharmaceutical industries in any country that adopted such a law. The cost of developing new drugs is too great to handle without secure rights to use the genetic materials (provided by contract arrangements) and inventions developed from them (provided by patents). No country aspiring to develop biotech industries could succeed if it diminished intellectual property rights as proposed by the mega-diverse countries.

Southern African countries reject 'TRIPs-plus demand in FTA negotiation.

Southern African Countries have rejected the European Free Trade Association's (EFTA), comprised of Switzerland, Norway, Iceland and Liechtenstein), proposal on intellectual property rights (IPR) in the free trade agreement (FTA) negotiation between the two trading blocs. They criticized the European bloc's proposed 'TRIPs-plus' provisions on public health and agriculture. The organizations contended that EFTA's pressure on SACU (SACU; South Africa, Botswana, Namibia, Lesotho, and

Swaziland) states to introduce a five-to ten-year data protection period for clinical test data, as well as a provision to potentially allow five-year patent extensions to brand-name drugs, would "block and delay generic competition," thus hindering access to medicine. They also criticized EFTA for asking SACU states to grant patents to "biotechnological inventions" and accede to the 1991 version of the UPOV convention (International Convention for the Protection of New Varieties of Plants), arguing that these measures would threaten the rights of Southern African farmers to use farm-saved seeds, thus threatening both biodiversity and food security. The South Africa approach for trade negotiation is always to seek the benefit of the community with SACU in all area of negotiation. As the SACU and EFTA have not able to agree on IPR, SACU suspended the negotiation of TRIPs-Plus Agreement. The Southern African Customs Union had refused to accept EFTA's proposed IPR provisions that went beyond the requirement of the WTO Agreement on Trade–related Intellectual Property Rights (TRIPs), said South African Trade Minister Mandisi Mpahlwa and a South Africa-based grassroots public health group.

Canada to allow generic medicine exports.

The Canadian government announced the patent laws to allow generic pharmaceutical companies to produce and export patent-protected drugs to those countries which are unable to manufacture their own generic drugs. The government's announcement followed the WTO General Council on a mechanism for relaxing the restrictions in the TRIPs Agreement (Article 31) on using compulsory licensing to produce generic medicines in one country for export to another. This initiative spurred a strong response, with Canadian NGOs, international organizations such as UNICEF, and health activists outside Canada in both developed and developing countries welcoming it. In contrast, the International Federation of Pharmaceutical Manufacturers Association criticized the initiative, saying it was premature and unhelpful.

Since the announcement, Canadian civil society organizations have called on the government to ensure that its legislation will fully implement the flexibility reflected in the WTO decision, and therefore will not be limited to exporting generic drugs for only certain diseases for countries facing health emergencies. They note that statements by government ministers have only referred to pandemics such as HIV/

AIDS, tuberculosis and malaria, and to helping countries facing emergencies. In its only public statement, the brand-name pharmaceutical industry association has stated that the WTO decision "relates to the provision of generic medicines to treat HIV/AIDS and other life-threatening diseases such as tuberculosis and malaria".

Indian trademarks and geographical indications laws enter into force

The Indian laws on trademarks and geographical indications entered into force as part of the country's effort to bring its intellectual property laws in line with the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs). The Trademarks Act 1999, which consolidates and amends the Trade and Merchandising Marks Act 1958, introduces the new concepts of 'service marks', i.e. a trademark for services, 'collective marks', which will allow associations to get registration for their marks, and 'well known-trademarks', which under specified criteria will receive higher levels of protection (irrespective of whether they are registered or used in India). The new Geographical Indications of Goods (Registration & Protection) Act 1999 provides for the registration and legal protection of geographical indications relating to goods in India. The Geographical Indications Registry, to be established in Chennai, is charged with administering the legislation and Appellate Board. Meanwhile the TRIPs committee also discussed in the meeting of June 2004,which took place in the context of geographical indications (GIs), in particular regarding the usefulness of GIs as a tool for protecting traditional knowledge (TK).

TRIPs council split over role of intellectual property to prevent 'biopiracy'

The WTO Council for Trade-related Aspects of Intellectual Property Rights (TRIPs) remained divided over the need to harmonize the TRIPs Agreement and the Convention on Biological Diversity (CBD) as a means for preventing 'biopiracy'. The relationship between the TRIPs Agreement and the CBD, the TRIPs Council received a new submission from Brazil on behalf of a group of developing countries, including China, Cuba, the Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe. The submission (IP/C/W/356) stressed the need to modify the TRIPs Agreement, arguing that the Agreement contained no provisions to prevent biopiracy acts or ensure prior informed consent and the fair and equitable sharing of benefits. To this end, the group of countries proposed several conditions for acquiring patent rights related to biological materials or TK, including requirements for patent applicants to disclose the source of origin of the biological resource and associated TK; and evidence of prior informed consent and benefit-sharing. The Brazil-led submission, however, stressed that the proposed requirements would only provide "defensive" protection of TK. Echoing similar proposals raised in related fora (i.e. the CBD, WIPO and preparations for the World Summit on Sustainable Development), the submission called on the TRIPs Council to also consider "positive" protection of TK, including, *inter alia*, an internationally agreed instrument that recognized national-level TK protection.

The trade delegates convened to continue their discussions on Article 27.3(b) (patentability of life forms), genetic resources, traditional knowledge and folklore in the WTO Council for Trade-related Aspects of Intellectual Property Rights (TRIPs). Despite continued efforts by developing countries to keep these issues on the table, the meeting made no real advances in the debate. The biodiversity-related discussions focused on the checklist of issues for further discussion that had been put forward by Bolivia, Brazil, Cuba, Ecuador, India, Peru, Thailand, Venezuela and Pakistan.

General Assembly bypassed in informal WIPO talks on patent harmonization.

The World Intellectual Property Organization (WIPO) member states met to discuss the continuation of the global patent harmonization process at Morocco. Many developing countries most of which were not invited were heavily critical of the meeting. They noted that Brazil was the only country among the 14 proponents of a 'WIPO Development Agenda' invited to the event, suggesting that this may have been an attempt to make support for the development agenda appear to be an isolated point of view. The other Southern representatives in attendance were from countries that have been passive in WIPO debates on the development agenda, or from states that are already committed by bilateral or regional trade agreements to intellectual property standards that go beyond those required by the WTO, such as Chile and Morocco. During the consultations, the approximately 20 countries and patent offices in attendance came up with an action plan for moving forward on patent harmonization, identifying six issues to be dealt with in an accelerated manner: prior art, grace period, novelty, inventive step, sufficiency of disclosure, and genetic resources. The meeting did make mention of the need to pursue a "robust, effective and actionable WIPO Development Agenda." Brazil was the only country to register opposition to the statement adopted at the end of the meeting.

Industrialized countries have recently been pushing the WIPO secretariat to move forward on patent harmonization. According to James Love, director of CPTech, an NGO focusing on IP issues, "the US, the EU and Japan are beating up on the WIPO Secretariat, insisting that it do what it can to get developing countries to do what they want on patent harmonization. They'll effectively take the Patent Cooperation Treaty out of WIPO by setting up a rival system..." The Patent Cooperation Treaty, which regulates the registration of global patents, is WIPO's main source of revenue

The parties participating in the Morocco meeting included: Brazil, Chile, China, France, Germany, India, Italy, Japan, Malaysia, Morocco, Russian Federation, Switzerland, the UK, the US, the African Regional Industrial Property Organization, Eurasian Patent Office, European Patent Office, African Intellectual Property Organization and the EU. Dr. R.A. Mashelkar, Director General of the Council of Scientific and Industrial Research and Secretary of the Department of Scientific and Industrial Research in India, chaired the meeting.

Patent regime not to affect prices of life-saving drugs

The Government of India has clarified that the new patent regime will not affect prices of the 350 essential (life-saving) drugs available in the market. As much as 97 per cent of the drugs available in the market are already off patent globally and are not likely to be patented in India. These drugs, therefore, would not experience any price increase, it claimed. According to a report, 3 per cent of the domestic pharmaceutical market were likely to get covered by patents in the coming months as the government took decision on mailbox applications. And, there are therapeutic alternatives for most of these drugs. The patentability criteria in the amended Act as it had 15 listed exclusions from patentability, including seeds and seed varieties. Once the Bill is introduced in Parliament changes would be incorporated in it. There are 9,000 patent applications in the mailbox with majority of them being from US companies. Although the number appears huge, only 2,500 applicants have followed it up with examination requests.

Patent law must fully reflect public health concerns: WHO

The World Health Organization (WHO) has observed that patent law in India does not reflect the concerns about public health as expressed in the Doha Declaration on TRIPs Agreement. The observation of the WHO is significant as the country is slated to amend its patent laws by January 1, 2005 as part of its obligation to WTO. Already several experts have suggested to the government to take the advantage of the flexibilities in protecting public health interests. The WHO study further said: "The grounds to realize the role of domestic enterprises in the availability and affordability of medicines are weak and need to be strengthened." It also said that Chapter XVI on compulsory licence in the Patents (Second Amendment) Act 2002 should have provided the possibility of the grant of voluntary licence to domestic enterprises by the foreign patentee who may not like to set up its own infrastructure in the country to promote its product.

The compulsory licensing system should aim at preventing the abuse of patent rights by the patentee in various regions of the country as sub-licensing is essential to country like India. The WHO report also said that the licensing system should be devised in such a manner so as to aid domestic companies to get licence from patent holder for commercial activity on reasonable commercial terms and conditions. The other important aspect about the scope of patentability needs to be formulated on basis of specific recommendations of the pharmaceutical research committee headed by the director-general of the Council for Scientific & Industrial Research (CSIR), Dr R.A. Mashelkar.

Gene campaign challenges European soyabean patent

Some multinational companies, scientists and non-government organizations (NGOs) have challenged the broad patent right granted by European Patent Office (EPO) to Agracetus (located in Middleton and founded in 1981 as part of Monsanto for R&D facility) for its claimed innovative particle bombardment (biolistic) method of transforming soyabean. The Delhi-based NGO Gene Campaign is one of those who deposed before the EPO in Munich. Syngenta and

DeKalb are amongst the multinational companies, which have opposed the patent rights to Agracetus. Greenpeace Germany, ETC-Canada, German Farmers Organization and a member from the Chinese scientific community also deposed before the EPO vouching for withdrawal of the conferred rights. The patent right in question was a very broad spectrum patent awarded on all existing genetically modified (GM) soyabean varieties and for all other GM crops where the same particle bombardment (biolistic) method was used. Such a broad patent right on GM cotton granted to Agracetus was struck down by the United States Patent Office said convener of Gene Campaign.

Novartis' case may spark patent vs patient debate

Novartis, the first pharmaceutical company to get an exclusive marketing rights (EMR) in India for its cancer drug, Novartis has heard from Indian patent office on the implementation of the Madras High Court order on giving the drug free to patients who cannot afford it. The company had received the letter from the Patent Controller. The company had given the anti-cancer drug free to about 3306 patients and only 45 were actually paying for the medicine. "On an average, about 30-odd patients enroll for the free cancer drug per week". The Government has asked Novartis for market related data on the drug, the pricing and number of patients who need it. This could be laying the ground for government's intervention if the price is found to be high and if patients have been denied the drug, said an industry representative.

Ever since the EMR was granted to Novartis, the company had taken legal recourse to get Indian companies to stop marketing copies of the same drug. A year's course of the anti-cancer drug Glivec internationally costs about $2700 (about Rs 11,61,000), while local copies from India at $2700 (about 1,16,100). Indian companies, on their part, too contested the EMR and the case is in the apex court. According to representative of pharmaceutical industry, the EMR is being contested. The Government of India could take up Novartis's patent application for the cancer drug.

Regulation of multiple gene products

On April 14, 2005, the Confederation of Indian Industries (CII) organized a meeting on 'Regulation of Biotech Crops: Going Beyond

Single–Gene Products'. Multiple gene products or stacks have more than one trait present in the same plant. For example, cotton plants containing a combination of herbicide tolerance and insect protection. Combined trait products have several benefits, including the ability to use the formerly approved single traits as building blocks for new products and improving the growth efficiency of a product. The meeting took place at a period when a draft policy for developing biotechnology, prepared by the Department of Biotechnology, was open for public comments.

Currently, India regulates only single gene products. So far, the only GM crop permitted for commercial cultivation in India is the Bt cotton, which is resistant to the bollworm. Similarly, countries such as Australia, China, Canada, Colombia, New Zealand, Russia and Taiwan regulate products at the single trait level. In the U.S., it is not mandatory to produce additional safety information on multiple trait products developed by conventional breeding if a single trait product is already approved and the traits are unrelated. In contrast, the European Union considers every stacked trait product as novel or unique, regardless of the status of the parent trait. Till date, no stacked trait product has ever been approved in the European Union.

Dr M.K. Bhan, Secretary, Department of Biotechnology, who delivered the keynote address, stated that in the midst of much controversies surrounding agricultural biotechnology it is important to have clearly articulated information on biosafety prepared by a neutral source that steers clear of advocacy. "The GEAC can contribute to disseminating knowledge by producing a manual that is accessible to the public," said Bhan, adding that "in order to create a more proactive structure, regulators should be available for consultation." He also stressed that the role of the decision-making body should be clearly distinguishable from that of the policy makers and suggested that the Ministry of Environment and Forests form a permanent policy board to look into policy related matters.

Sharing his experiences with large scale trials, Dr C.D. Mayee, Chairman, Agricultural Scientist Recruitment Board, pointed out that 55 different trials on Bt cotton were carried out at 11 locations around the country prior to its approval in 2002. Mayee stated that, "Multi-locational Cry 1AC trials should be abolished since a lot of trials have already been conducted and since there is serious land shortage." Instead, he felt that the field trials should focus on new genes. He also stated the practical difficulties faced by the Monitoring and Evaluation

Committee in visiting and inspecting the field trials carried out at different locations in the country.

DD Verma, joint secretary, Ministry of Environment and Forests stated that India is among the world's 17 megadiverse countries. The conservation and sustainable management of such a rich genetic diversity, he maintained, consequently contributes to greater prospects in agricultural biotechnology.

Dr Philip J Eppard, Regulatory Affairs Lead, Monsanto elucidated the different country regulations on stacks or combined trait products. Eppard explained that stacks maximize the benefits of biotechnology, by helping the "growers realize the benefits of each trait without having to forego benefits of another trait." Eppard further added that the lack of a globally recognized food, feed and environmental safety assessment paradigms on stack products is one of the many challenges in its development. He further stressed the need for a scientific approach for the regulation of conventionally bred stacks.

Dr S.R. Rao, Ministry of Science and Technology, who presided over the second half of the meeting explained the need to focus beyond the confines of risk assessment, and echoed the concerns of Dr M.K. Bhan by stressing the need to address issues of biosafety to the public through information generation and dissemination. Dr Rao also added that scientists as well as professors have a responsibility in strengthening the current low level of public knowledge on biosafety.

Presenting the industry's point of view, M Prabhakar Rao, Managing Director, Nuzeevedu Seeds Pvt Ltd, expressed concern about the GEAC having to deal with applications concerning hybrids with approved gene as well as hybrids with new or unapproved genes under the same platform. "A sub-committee should be formed under the GEAC to test the release of new hybrids," asserted Dr Rao. He reiterated Mayee's statement that it is not necessary for a hybrid that is already approved to go through an approval procedure before the GEAC. Dr. Rao also suggested the formation of a sub-committee of stakeholders under the aegis of the Genetic Engineering Approval Committee or the Department of Biotechnology to deal with subject based issues.

One of the main subjects of discussion was whether biosafety risk assessment should be differentiated from agronomic performance. This ambiguity, according to several participants, is a dilemma that has contributed to the increasing workload of the GEAC and the RCGM where a lot of time is spent attempting to sort out problems related to agronomic performance. In the process, less time is spent on 'real issues' such as biosafety and issues related to food and feed. The need for risk assessment to be based on scientific knowledge and rationale and not process oriented was also strongly articulated. One of the participants stated the importance of having a formal risk assessment document of approved products in place, simultaneously lamenting the lack of available scientific documents prepared by the government.

Dr K R Khetrapal, head, division of plant quarantine, National Bureau of Plant Genetic Resources, expressed concern over the absence of several mechanisms in India, including trade policies on genetically modified organisms (GMOs), that is significant in order to operationalise the Cartagena Protocol on Biosafety (CPB), to which India is a signatory. The CPB is an internationally binding legal agreement that regulates the transboundary movement of GMOs that may have adverse effect on the biological diversity and human health. These concerns, he felt, have strong implications since the recent WTO meetings have increasingly focused on the biosafety and trade interface.

Emphasis on stringent regulation on biotechnology is a futile exercise, particularly when illicit or unapproved Bt cotton is already cultivated in more than six lakh acres of land, a clear reflection of the government's failure to control its proliferation, stated a participant, who felt that the decision should be left to the farmer who is the best judge. At the same time, there were strong opinions regarding the need for regulation, particularly in the case of stacks, since there is a probability of environmental harm.

(Source RIS based on *Check Biotech*, October 5, 2004; *Hindu Business Line* February 18,2005; *Check Biotech* November 10, 2004; *Check Biotech* November 16,2004; *Check Biotech* November 18, 2004; *Crop Biotech Update* November 19,2004; *BRIDGES Weekly* November 24,2004; *BRIDGES Weekly* December 8, 2005;*Crop Biotech Update* January 7,2005; *Check Biotech* January 11,2005; *Check Biotech* January 18, 2005; *Check Biotech* January 21,2005; *Check Biotech* January 24,2005;*Deccan Herald* January 29,2005; *Check Biotech* February 7,2005;*Crop Biotech* February 2005; *Check Biotech* February 18, 2005; *BRIDGES Weekly* March 9,2005;*BRIDGES Weekly* October 15,2003; *BRIDGES Weekly* September 25,2003; *BRIDGES Trade BioRes* July 11,2002; *BRIDGES Trade BioRes* June 25,2004; *BRIDGES Weekly* February 23,2005.*Financial Express* January 6, 2005; *Financial Express* November 25,2004; *Financial* Express May 08, 2004; *Financial Express* June 23, 2004; *Hindu Business Line* February 18,2005; and Report by Lian Chawii).

Document

We present herewith a brief outline of the OECD Draft guidelines for the licensing of genetic invention.

Biotechnology and genetics research have been the subject of extensive investment by both the public and private sectors. The products and processes emerging from these efforts make a significant and increasing contribution to human health and health care. The science and health ministers of the OECD member countries concluded that biotechnology would be a key driver for sustainable growth and development. Biotechnological, including genetic, innovations have been the subject of intellectual property rights for decades. Over the last decade, as the number of such innovations has increased their use in and importance for the human health care field has also grown. Recently, some countries have expressed concerns with how certain genetic inventions have been licensed and exploited, particularly for diagnostic genetic services in the human health care field.

These Guidelines offer principles and best practices for the licensing of genetic inventions used in human health care. They are targeted at all those involved with innovation and the provision of services in health, and particularly at those involved in the licensing of such inventions. The Guidelines are intended to assist both OECD and non-OECD governments in the development of governmental policies as well as in their efforts to encourage appropriate behaviour in the licensing and transferring of genetic inventions. Overall, the Guidelines seek to foster the development and delivery to the market of products and services based on genetic innovations, such as therapeutics and diagnostics, in order to more effectively and efficiently address health care needs in both OECD member and non-OECD countries.

These Guidelines apply to the licensing of intellectual property rights that relate to genetic inventions used for the purpose of human health care. Within these Guidelines, the term "Genetic Invention" includes nucleic acids, nucleotide sequences and their expression products; transformed cell lines; vectors; as well as methods, technologies and materials for making, using or analysing such nucleic acids, nucleotide sequences, cell lines or vectors. This definition is intended to be forward looking to encompass highly related future developments.

Genetic Innovation and Human Health Care

Advances in biotechnology and genetics offer much promise for sustainable growth and development of economies and for society more broadly. Genetic innovations already play an important role in meeting health needs. Future advances will provide a better understanding of the interaction between environmental factors and genetic heritage, will lead to the development of new products and services, including diagnostic tests, therapeutics, and medications, and will contribute to more effective and efficient delivery of high quality health care more generally. Efforts need to be made to ensure that these advances deriving from a better understanding of genetics are made available to those who stand to benefit, both in developing and developed countries.

Progress in genetics and health-related biotechnology is not only increasingly valuable to health care, but also represents a significant and growing portion of OECD member states' economies. Developments in the field of genetics may also provide society with important results that may be transferred and may stimulate knowledge spillover effects of importance to the economy at large, both in developing and developed countries.

The genetics and genomic revolution and the development of products and services that has happened in its wake have been due to the work both of the public and private sectors, individually and in collaboration. Research thrives on collaboration and getting the most out of the genetics revolution will rely increasingly on efficient and effective exchange between those researching and developing new innovations – as well as with those that would use these innovations. It is this spirit of exchange and cooperative effort that lies at the core of these Guidelines.

Balanced Intellectual Property System

Innovations, in the field of genetics as elsewhere, are typically protected via various forms of intellectual property rights. Most commonly, inventions are the subject matter of patents. However, innovations may also be protected through laws preventing the unauthorized transfer of undisclosed information, and through contractual provisions, such as those in material transfer agreements.

Generally, the patent system and other forms of intellectual property aim to encourage the development and dissemination of knowledge and innovations with a view to fostering scientific, technical and social progress for the betterment of society. While a rights holder may choose to exploit or commercialize such innovations directly, often these are exploited or commercialized via licensing agreement, joint development activities or through material transfer agreements. Such agreements or activities allow the operation of the intellectual property system as they not only promote the commercialization of and access to innovations, but also provide rights holders with the ability, if they wish, to achieve a return on their investment. Each of these functions constitutes an integral part of a balanced intellectual property system.

While there is no single model for the licensing or transferring of genetic innovations, the manner in which rights holders choose to carry out such activities has and will increasingly have implications for future research and development, especially involving fundamental or new technologies, as well as for access to the latest medical innovations. These Guidelines aim to provide parameters so as to ensure that licensing and material transfer agreements as well as joint development activities are based on economically-rational practices, that help eliminate high transactions costs in line with competition law, and that serve the interests of society, shareholders and other stakeholders.

The preamble of the Guidelines offer principles and best practices for the licensing of genetic inventions used in human health care. It also seeks to foster innovations, such as therapeutics and diagnostics, in order to more effectively and efficiently address health care needs in both OECD member and non-OECD member countries. Again the guidelines apply to the licensing intellectual property rights that relate to genetic inventions and innovation. It approaches the balance between intellectual property system and nature of invention. As the patent system and other forms of intellectual property aim to encourage the development and dissemination of knowledge. The Preamble has two parts,

Part 1: Principles and best practices for the licensing of genetic inventions

The Guideline contains explanatory annotation for each section of principles and best practices. The Guidelines are proposed to assist both OECD and non-OECD governments in the development of governmental policies and efforts to support appropriate behaviour in the licensing and transferring of genetic invention. The principle provides a framework within which to conceive of voluntary, market–oriented licensing arrangement with respect to genetic inventions used for the purpose of human health care. The principles of general licensing practices should foster innovation in the development of new invention related to human health care and should ensure therapeutics, diagnostics and other product and services employing genetic invention. While there is no single model for the licensing or transferring of genetic innovations, the manner in which rights holders choose to carry out such activities has and will increasingly have implications for future research and development, especially involving fundamental or new technologies, as well as for access to the latest medical innovations. These Guidelines aim to provide parameters so as to ensure that licensing and material transfer agreements as well as joint development activities are based on economically-rational practices that help eliminate high transactions costs in line with competition law, and that serve the interests of society. The impact on access to information, products and services for researchers, clinicians and patients resulting from an increase in patent applications filed and patents granted for genetic inventions used in human health care as well as the associated licensing practices for such inventions. This development of guidelines for the licensing of genetic inventions was a priority. The needs and concerns of all those involved with innovation and the provision of services in health, and particularly at those involved in the licensing of genetic inventions. These include, but are not limited to, public and private sector entities involved in the licensing or transfer of biotechnological inventions, health authorities, patients and patients groups, researchers, clinicians, and intellectual property rights holders.

Part 2: Annotations

The rise in the number of patents for genetic inventions can be a sign of dynamism in a new technological sector. The Guidelines apply to licensing of intellectual property rights that relate to patents, undisclosed information, trademarks and copyright. Its also pertains to genetic inventions, which should foster economic growth through the innovation and substantive competition. In the area of genetic testing, the researcher has faced situations of difficulty in obtaining licence for reasonable fee. The principles provide that licensors and licensees should aim for the rapid dissemination of information about the nature and uses of the genetic inventions. It recognizes the importance for licensors and licensees to obtain a commercial return on their investment with respect to genetic inventions.

It also recognizes the importance of licensors and licensees being encouraged to consider the best possible impact of their license arrangement on the health care system and on patients. The licensing practice should also promote the strong research environment and market for health care products and services. The healthcare product and services as well as the use of genetic inventions may be subject to a variety of rules, standards and regulations regarding privacy, safety and good laboratory methods. The genetic invention facilitates the innovative uses in clinical and research areas while maintaining or expanding the economic return to the licensor.

The principles recognize the importance of competition law as a complementary means of achieving a strong research and development base with respect to genetic invention. It also encourages the licensees and licensors to become aware of the application of these laws and best practices and independent assessment. The contractual provisions as non-compete or similar clauses discourage the innovation and restrict competition. It encourages the exploitation of licensed technology for the development or commercialization of new products or services. Thus, it is suggested that licensors and licensees evaluate the practical effect of non-compete clauses on the ability for new products and services to enter the marketplace. The strong research base and as, a supplement to competition law, licensors should consider licensing those genetic inventions that comprises base. The best practice also assists the mechanism of patent pools; patent clearinghouses or standard contractual provisions.

Bio Web

The intellectual property protection has attracted major attention after the TRIPs regime. Several interesting scientific discoveries are going on and the intellectual property protection has been playing a significant role for the new invention and for the inventor.

http://www.wipo.org/

The World Intellectual Property Organization (WIPO) is an international organization dedicated to promoting the use and protection of works of the human spirit. The words intellectual property are expanding the boundaries of science and technology and also enriching the world of the arts. WIPO plays an important role in enhancing the quality of life, as well as enhancing economies of nations. Based in Geneva, Switzerland, WIPO is one of the 16 specialized agencies of the United Nations system of organizations. It administers 23 international treaties dealing with different aspects of intellectual property protection. The Organization is composed of 182 nations.

http://www.nipoonline.org/

National Intellectual Property Organization (NIPO) of India plays an important role in increasing awareness about the rights of intellectual property (IP) owners and regulators through legal or professional practice. NIPO promotes development of infrastructural facilities for registration of intellectual property by facilitating the improvement of legal, institutional and administrative framework. It assists and facilitates owners of intellectual property and fosters ties of mutual friendship and understanding among those practioners in the field of intellectual and industrial property law and through such ties promotes the protection and development of intellectual and industrial property in India.

http://www.tifac.org.in/

The Technology Information, Forecasting and Assessment Council (TIFAC) is an autonomous organization of Department of Science and Technology, under Ministry of Science and Technology, Government of India. TIFAC undertakes technology assessment and forecasting studies in selected areas of national economy. It assesses the global trends and undergoes formulation of preferred options for India. It also plays an important role in the promotion of key technologies, and provides information on technologies and patent filing facility. The large knowledge base of academic institutions and research and development agencies needs more information, orientation and facilities for protecting the products of intellectual prowess of Indian scientists. There is a single window Patent Facilitating Cell under TIFAC whose activities are aimed at providing patenting facilities to scientists and technologists, keeping a close technology watch by taking up patent analysis in specific areas and creating awareness and understanding of patents among the scientific community by arranging workshops and seminars.

http://www.nrdcindia.com/

The National Research Development Corporation (NRDC) is India's premier technology service enterprise which functions as the identifier, the carrier and the pilot of technology transfer. NRDC has played a key role in spreading the commercial applications of research and in effecting the transfer of technology from laboratory to enterprise. It provides business and other critical information to companies and research institutes across the country. NRDC has maintained its position among the top information providers on intellectual property rights (IPRs). Its analysis of patent and scientific data and IPR solutions have met the needs of corporations and, equally important, fulfilled the technological demands of the country. It provides the following facilities like national patent protection scheme, foreign patent protection scheme, online search facility, commercializing patented inventions, consultancy on IPR, organizing IPR awareness programmes and IPR help line.

http://www.patentmatics.org/

This is a website exclusively devoted to propagating the science, technology and management of Intellectual Property Rights in general and of Patents and Patenting Practices particular in India. It is also concerned with the development of research, industrial/commercial activities and policy planning programmes. Intellectual Property Rights (IPR's), of which patents form the major component, are protected and enforced akin to all forms of private property through appropriate domestic laws with the cherished aim of encouraging scientific-technological innovations of new products and processes leading to increased societal wealth and prosperity.

http://www.patentoffice.nic.in/

The Indian Patent Office is established by the Government of India and is equipped with patent filing facilities. The Office of the Controller General of Patents; Designs & Trade Marks (CGPDTM) supervises the working of the Patents Act, 1970, as amended, the Designs Act, 2000 and the Trade Marks Act, 1999 and also renders advice to the Government on matters relating to these subjects. The Patent office put in place a patent regime that allows the grant of patents for both products and processes for all eligible inventions. The changes made in 1999, 2002 and 2005 apparently comply with its WTO obligations on intellectual property.

http://www.european-patent-office.org/

The European Patent Organization (EPO) is established by the Convention on the Grant of European Patents. The EPO is the European countries' collective political determination to establish a uniform patent system. It is a centralized patent grant system administered by the European Patent Office on behalf of all contracting states. The European Patent Office (EPO) grants European patents to the contracting states.

http://www.ipo.com/

Intellectual Property Owners Association (IPO) is a trade association for owners of patents, trademarks, copyrights and trade secrets of the United States. IPO is the only association that serves all intellectual property owners in all industries and all fields of technology. The association advocates effective and affordable IP ownership rights and provides a wide array of services to members. It provides support to its members on relating to legislation, analyzing current IP issues, providing information, educational services and disseminating information to the general public on the importance of intellectual property rights. IPO advocates effective protection for patents, trademarks, copyrights, and trade secrets.

http://www.patent.gov.uk/

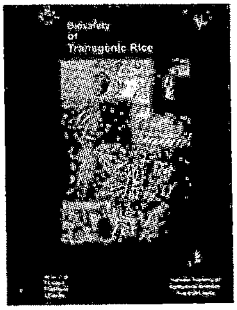
The Patent Office is responsible for developing and carrying out UK policy on all aspects of intellectual property. The Intellectual Property and Innovation Directorate (IPID) deals with the policy for patents, copyright (and related rights), trade marks, designs and geographical indications of origin, and co-ordinates on issues affecting both copyright and industrial property matters. It works to create an environment that facilitates the effective enforcement of intellectual property rights in the UK and overseas.

http://www.jpo.go.jp/

The Japanese Patent Office consists of General Affairs Department, Examining Department, Trial Department, General Information Office for Industrial property rights, and other sections and departments. The system of industrial property rights of Japanese patent office is to contribute to development of industry by securing and protecting the successful and creative development of structures for patents, etc. The role of the Patent Office is to deal with the development in the entire industrial sphere through its system for industrial property rights, including examinations, trials, and designing of plans.

http://www.csir.res.in/

The Council of Scientific and Industrial Research (CSIR) is an autonomous research organization of the Government of India. The Intellectual Property Management Division (IPMD) of the CSIR plays a vital role on behalf of the performance of CSIR in channelling science for exploiting it for economic advantage. It files patents annually and owns more Indian patents than any other organization in the country. It is envisaged that CSIR will hold a valuable portfolio of Indian and foreign patents which will enable it to strike strategic alliances with some of the global technological leaders in specific areas. The IPMD of CSIR would be the national resource and an international reference centre on IP matters.



Biosafety of Transgenic Rice. 2005.

Chopra, V.L., S. Shantharam and R.P. Sharma (Eds).,
National Academy of Agricultural Sciences, (NAAS),
New Delhi, India. 237 pages. Rs. 500.00.
ISBN : 81-900426-1-4

The present book explores the potentialities of genetic engineering as a powerful tool for crop improvement. It mainly provides a broad overview of the recent advancements of transgenic rice' which have opened up new avenues for harnessing the process of developing designer crops for meeting both food and nutritional requirement of the human beings.

The book contains edited papers along with the recommendations presented in the Rice Biosafety Workshop, 2002, sponsored by Syngenta International, Switzerland and NAAS, India. It basically brings together representatives from industry, academia, and other stakeholders to discuss various issues and concerns regarding commercialization of transgenic rice. Despite the production of more than a dozen transgenic rice' varieties and introduction of genes for herbicide tolerance and pest resistance by a large number of research laboratories in India as well as in both developed and developing countries, not even a single transgenic rice has been released for commercial production for various reasons.

The book includes extensive wealth of information about the development of genetically engineered rice and raises an important issue regarding the urgent need to develop consensus on scope and limitations for the commercialization of transgenic technology.

— ***Beena Pandey***

Bio Stat*

Biotechnology Patent Statistics in US, EU, Japan and India

Life sciences and biotechnology are widely recognized as most promising and frontier technologies in the new knowledge-based economy. Biotechnology has captured the attention of all nations. Every country is prepared to spend large funds to promote research and development in biotechnology. In biotechnology inventions typically require high capital investments and it is generally recognized that effective patent protection is a crucial incentive to R&D and innovation.

The EU and US apply for patent at the European Patent Office (EPO) for the classes C12N (biotechnology) and C12N15 (genetic engineering)[1] from 1996 to 2000.The US filed the largest number of patents applications (4129) at the EPO in the biotechnology sector (around 45.4 per cent of total), followed by the EU Member States 3497 (around 38.8 per cent). Japan filed only around 817 (9 per cent) of patents in this period. Both EU Member States and the US increased their patent shares from the 1986-1990 to the 1996-2000 periods, with somewhat larger increases by the US.

At the US Patent and Trademark Office, the majority of patents granted in the genetic engineering sector between 1994-1997 went to US inventors (72.5 per cent). EU Member States had a 14.5 per cent share and Japan a mere 7.5 per cent. While the US and Japan shares both dropped by about 3 percentage points from the 1984-1987 period, the EU Member States increased their share by 3.5 per cent. The data (Table 1) shows that EU Member States clearly lag behind the US in patenting activity. The EU Member States are not only behind the US

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* Prepared by Bijoy Kumar Sahu.

Table 1: Country shares of patent applications in the biotechnology/ genetic engineering sectors at the EPO compared to patent grants at the USPTO

Country	EPO applications				US grants	
	Biotechnology (C12N)		Genetic Engineering (C12N15)		Genetic Engineering (USPTO definition)	
	1986-1990	1996-2000	1996-2000 (Per cent)	1986-1990 (Per cent)	1994-1997 (Per cent)	1984-1987 (Per cent)
EU	37.4	38.3	38.3	36.6	14.5	11.0
Japan	19.6	9.0	8.5	17.5	7.5	10.8
US	38.4	45.4	46.3	41.1	72.5	75.4
Others	4.6	6.8	7.0	4.7	5.4	2.8

Source: Report from Commission to the European Parliament and the Council. Brussels.

in protecting their European markets, but also they have a comparatively small share of patents in US technology. Currently, the EPO is handling about 60 per cent of all international applications, 50 per cent of which come from the US. To ease the situation, the EPO has decided not to accept from US residents, under the Patent Cooperation Treaty (PCT), any application directed to biotechnology.

In India, patent filing in the area of biotechnology is based on the applications filed in the Indian Patent Office from 1995 to June 2003. A large set of scientific keywords and careful analysis of titles were utilized for capturing the applications in the area of biotechnology. A total of 2378 patent applications have been filed in India till June 2003. Out of 2378 applications, 716 are conventional applications and 774 are PCT applications.[2] The maximum number of applications is 451, which were filed in the year 2001 (Table 2). The Council of Scientific

Table 2: Trend in Biotechnology Patents in India

Year	Number of Patents
1995	172
1996	193
1997	279
1998	287
1999	162
2000	265
2001	451
2002	395
20003 (Jan.- June)	155

Source: IPR Bulletin, Vol.10, and NO 6-7, June-July 2004, TIFAC, New Delhi.

Table 3: Biotechnology Patent filed till June 2003

S.No	Area	No. of Patents field till June 2003
1	Protein + Enzyme	700
2	Bacteria+ Bacillus	236
3	Fungi (includes fungicides)	219
4	Virus	162
5	Therapy	138
6	Gene	136
7	Vaccine	123
8	Sequence	120
9	Nucleic acid +RNA	115
10	Fermentation	109
11	Antigen	88
12	Vector (Plasmids and Phages)	66
13	Mutation	54
14	Transgenic	47
15	Microorganism	45

Source: *IPR Bulletin*, Vol.10, and NO 6-7, June-July 2004, TIFAC, New Delhi.

and Industrial Research (CSIR) is the single major applicant in this field, with 202 patents filed in its name.

The main areas in which patents are filed in India are hybrid (44), tissue culture (15), embryo (18), cell line (10), enhancer (27), marker (31), transformation (33), promoter (40). Many of these applications may be products, drugs/pharmaceuticals, genetically modified microorganisms, naturally occurring RNA/nucleic acids and genes. As per the current position, such applications may not qualify for grant of patents in India. Some of these may be taken as mailbox applications. The number of patent in micro-organism related applications are around 800. The protein, the product of genes has opened a new branch in biotechnology-proteomics. In the area of proteins, 700 patent applications were filed till June 2003, out of which 240 applications were convention applications and 228 were PCT applications. These applications also include 245 patent applications for enzymes. A closer look at patent applications in the field of protein year wise; for instance, they were 69 in 2000 and about 135 in the next year.[3]

Endnotes

1 Definition of "genetic engineering" differ between the USPTO and EPO due to different classification systems.

2 *TIFAC Bulletin*, Department of Science and Technology, Govt.of India, June-July 2004.

3 ibid.

Announcement

Asian
Biotechnology
and
Development Review

Vol. 7 No. 3 July 2005

Capacity Building Activities in Biosafety

***Guest Editor:* S. R. Rao**

Guest Editorial

- How Do We Get the Job Done? An Overview of Capacity Building and Priorities in the Asia-Pacific Region
  J. I. Cohen
- Involving the Public Research Sector in Regulations and International Agreements Relevant to Biotechnology
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- Agricultural Biotechnology in Developing Countries: Nature and 'Code in Meeting the Needs of Resource Poor
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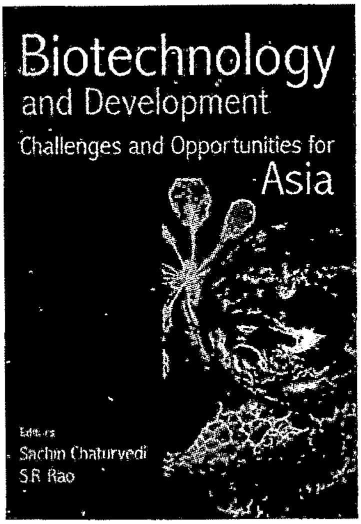
  Chris Viljoen
- ICGEB in Capacity Building Activities of Biosafety in Developing Countries
  Mark Tepfer
- Biotechnology Product Development Partnerships: Emerging Institutional Capacities in East Africa
  John Komen

Announcement



Biotechnology and Development: Challenges and Opportunities for Asia

Editors:
Sachin Chaturvedi and S.R. Rao

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BIOTECHNOLOGY along with the other core technology viz. Information technology, is at the heart of technology revolution in Asia. Asian countries have adopted statrategies for harnessing the potential of biotechnology for their industrial development. The areas of applications both in pharmaceutical and agriculture sector have widened, finding new vistas of economic growth.

Policy challenges, however, are arising among others, concerning trade in GMOs, impact of genetic engineering on environment and human health, biosafety management, and ethical aspects that are yet to be addressed at any collective forum in Asia. One of the missing links is a dialogue between natural and social scientists so as to identify socio-economic requirements and policy priorities in the realm of biotechnology and development in the region.

This book brings together perceptions on some of these issues by eminent experts from the Asian region. As a sequel to the pioneering Biotechnology Revolution and the Third world: Challenges and Policy Options (RIS 1988), this volume draws lessons from the experiences of Asian developing countries and revisits some of the concerns raised earlier.

The contributors to the volume draw policy lessons from country experiences in capability building in Asia, in particular on the role of regional cooperation. It is clear that the Asian countries need not only technical assistance for capacity building, but also financial support to upgrade their facilities to meet challenges emerging from the introduction of new organisms. As most of the Asian economies face common challenges including the management of biodiversity resources, cooperative efforts may prove fruitful. An examination of regional cooperation in Europe and ASEAN may help in identifying a roadmap. Volume Editors present a synthesis of key lessons emanating form differnt contibutions.

Biotechnology and Development: Challenges and Opportunities for Asia is a valuable resource for governments, multilateral institutions, academics and practitioners in the field of economic development and technology policy management.

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(c) **Articles from edited volumes:**
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